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CORRESPONDENCE

(1977)

10.2



Association of American Cancer Institutes

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Durham, North Carolina

Vice President
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Comprehensive Cancer
Center for the State of
Florida
Miami, Florida

Secretary-Treasurer
Edwin A. Mirand, Ph.D.,
D.Sc.
Roswell Park Memorial
Institute
Buffalo, New York

October 11, 1977

10.20
Bgt
JH
✓
11/28

Dr. Donald S. Fredrickson
Director
National Institutes of Health
Bethesda, MD 20014

Dear Dr. Fredrickson:

Association of

I write in behalf of the membership of the ~~Association~~ Association of Cancer Institutes to indicate their overwhelming sentiment against conducting a clinical trial of Laetrile because there is no apparent sound scientific basis for such an undertaking.

After considering the matter in some detail, the Clinical Research Committee of our organization adopted a resolution which was later approved by the Board of Directors and submitted to the membership. Of the 37 institutions answering the poll, all but 4 expressed their unequivocal opposition to a trial. Those who would "go along with a trial" indicated that they were yielding to the current public clamor and not responding to the same sort of objective evidence that would be required of all other potential anticancer compounds.

We submit this expression of opinion to you, hoping that it may serve a constructive purpose. In the course of discharging your responsibilities, doubtless you receive many expressions of opinion. In this case, the Association thought you might like to know the thoughts of several individuals who play important roles in our national cancer effort.

many

Sincerely,

Albert H. Owens, Jr., M.D.
Chairman, Board of Directors

AHO:bg

cc: Board of Directors

BOARD OF DIRECTORS

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association of american cancer institutes

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Houston, Texas

Lewis L. Coriell, M.D.
Camden, New Jersey

~~XXXXXXXXXX~~
~~XXXXXXXXXX~~

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

Alvin M. Mauer, MD
Memphis, Tenn.

October 31, 1977

Dr. Arthur C. Upton
Director
National Cancer Institute
Bethesda, MD 20014

Dear Dr. Upton:

I write in behalf of the membership of the Association of
Association of Cancer Institutes to indicate their overwhelming
sentiment against conducting a clinical trial of Laetrile
because there is no apparent sound scientific basis for such
an undertaking.

After considering the matter in some detail, the Clinical
Research Committee of our organization adopted a resolution
which was later approved by the Board of Directors and submitted
to the membership. Of the 37 institutions answering the poll,
all but 4 expressed their unequivocal opposition to a trial.
Those who would "go along with a trial" indicated that they were
yielding to the current public clamor and not responding to the
same sort of objective evidence that would be required of all
other potential anticancer compounds.

We submit this expression of opinion to you, hoping that
it may serve a constructive purpose. In the course of discharging
your responsibilities, doubtless you receive many expressions of
opinion. In this case, the Association thought you might like
to know the thoughts of several individuals who play important
roles in our national cancer effort.

Sincerely,

Albert H. Owens, Jr.

Albert H. Owens, Jr., M.D.
Chairman, Board of Directors

AHO:bg

cc: Board of Directors

10.2
October 18, 1977

Dr. William W. Shingleton
President, Association of American
Cancer Institutes
Duke Comprehensive Cancer Center
Duke University Medical Center
Durham, North Carolina 27710

Dear Bill:

I would like to recommend Dr. C. B. Jackson, Director of Extramural Programs, at our institution as the AACI liaison representative to the American Blood Commission. Doctor Jackson, who is a hemo-oncologist, has worked extensively in the blood program with the Institute of Hemotherapy in Houston and has advised and assisted me in many areas of the blood program for the American Cancer Society.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC:jh
cc: Dr. C. B. Jackson



association of american cancer institutes

OFFICERS

President
William W. Shingleton, M.D.
Duke Comprehensive Cancer
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Durham, North Carolina

Vice President
C. Gordon Zubrod, M.D.
Comprehensive Cancer
Center for the State of
Florida
Miami, Florida

Secretary-Treasurer
Edwin A. Mirand, Ph.D.,
D.Sc.
Roswell Park Memorial
Institute
Buffalo, New York

MEMORANDUM

TO: Cancer Center Directors
FROM: William W. Shingleton, M. D.
DATE: September 26, 1977
RE: American Blood Commission

The AACI is in need of naming a new liaison representative to the American Blood Commission. I am seeking your help in identifying someone from our member organizations who is actively involved in blood banking and/or hemotherapy with knowledge of modern requirements for patient service, especially as they relate to the needs of cancer patients. I would appreciate hearing from you with any recommendations you might have.

BOARD OF DIRECTORS

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Houston, Texas

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Camden, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

OK
Jackson ?
ask him.

4'd be happy to represent the AACI

J.L.

Bice



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20814

NATIONAL CANCER INSTITUTE

September 22, 1977

10.2

Dr. William W. Shingleton
Director, Comprehensive Cancer Center
Duke University Medical Center
P.O. Box 3814
Durham, North Carolina 27710

Dear Bill:

This will serve to confirm our invitation to have you, Al Owens and Gordon Zubrod as representatives of AACI, meet with the NCI Executive Committee on November 17, 1977. I understand that our customary meeting time, 9:00 a.m., will be suitable for all of you. However, if this later turns out to present any problem, we would be glad to move the time back a half hour or hour. The meeting will be held in our conference room, 11A10, Building 31. Although I suspect that our business can be completed during the morning, we shall hold the room until midafternoon.

We would be pleased to have your suggestions for items that you would particularly like to discuss with the Committee, so we can pull together any background information that would facilitate such discussions.

To refresh your memory, the Executive Committee is NCI's senior internal management and program advisory group. It is composed of the Division Directors, Dr. Upton, Dr. Newell and several other members of the OD staff.

We are looking forward to our meeting with you. Please give me any thoughts you have on how we can best structure the meeting to deal with the matters of greatest interest to you.

With best wishes.

Sincerely yours,

Bud

Bayard H. Morrison III, M.D.
Assistant Director

cc: Dr. Owens
Dr. Zubrod

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

10.2

Ed.

September 22, 1977

Dr. William W. Shingleton
Director
Comprehensive Cancer Center
Duke University Medical Center
Durham, North Carolina 27706

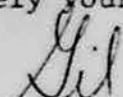
Dear Bill:

It was a pleasure to join you in the meetings this week of the NCI Board. The combination of business discussions with the instructive reviews of environmental carcinogens and of potential applications of computed tomography made an instructive and stimulating time.

I enjoyed our discussions about the centers, Bill, and I hope that significant review of the overall centers program will be possible as the data from the profiles and the visits are accumulated.

Best wishes.

Sincerely yours,


Gilbert S. Omenn, M.D., Ph.D.
Assistant Director for Human
Resources and Social and
Economic Services

100-111

MEETING OF REPRESENTATIVES
Association of American Cancer Institutes
and
Organization Resources Counselors, Inc.

Date and Location

Wednesday, July 20, 1977
ORC Offices
1625 I. Street, N.W.
Washington, D. C. 20006

Present

ORC Mr. Mel Garcia, Tenneld, Inc., Houston, Texas
Dr. Rufus Miller, General Motors, Detroit, Michigan
Mr. Wayne Brooks, ORC, Washington, D. C.
Dr. Bruce Karrh, DuPont, Wilmington, Delaware
Mr. B. K. Kwon, ORC, Washington, D. C.
Dr. Clifford Johnson, Goodyear, Akron, Ohio
Mr. Dennis Bridge, Baxter Labs, Deerfield, Illinois
Mr. C. S. Ryan, Sunoco, Philadelphia, Pennsylvania

AACI Dr. J. Palmer Saunders, University of Texas, Galveston
Dr. William W. Shingleton, Duke Medical Center, Durham,
North Carolina
Dr. Albert H. Owens, Johns Hopkins University, Balti-
more, Maryland
Mr. H. D. Putney, Fox Chase Cancer Center, Philadelphia,
Pennsylvania
Dr. Gordon Zubrod, University of Miami, Miami, Florida

The following statements are excerpts taken from my notes of the meeting and as such do not constitute minutes of the meeting, but are my recollection of the gist of the discussions. Obviously, there are errors or omissions which should be corrected or supplemented by others.

OPENING REMARKS

Mr. Brooks referred to the concern by industry about the cancer problem - that "the cancer problem is the work-place" - and industry's desire to mount a research program to study the cancer problem as it impinges upon or affects American industry.

Dr. Shingleton responded by giving a brief resume of the history of the AACI, the impact of the National Cancer Act and the development and role of cancer centers in the National Cancer Program. He also described the Environmental Carcinogenesis Conference at Houston in January 1977 and stated that the proceedings of the Conference will be published. His point was that the Conference had evoked a genuine concern on the part of the AACI and that there was a consensus of the Association that it might play a role as a catalyst in the development of a program for the study of environmental carcinogenesis between the Federal government (NCI), industry (ORC), and science (AACI).

DISCUSSION

1. The Right to Publish

In answer to Dr. Saunders' query concerning the right to publish, various spokesmen (Dr. Karrh especially) from industry emphasized their willingness to ensure that this privilege be granted. They felt that "industry would want the right to the information first - that industry/management doesn't want to be surprised." Further, all of the representatives emphasized their convictions of the "right of the worker to know" and the ramifications of the Privacy Act which could present a problem vis-a-vis dissemination of medical record information. Concern was expressed that oft times there is a need to know the name of the individual.

2. Union Relationships

Unions need (or will have to be brought) into the picture early. There are, however, diverse relationships which must be recognized, thus making the timing for discussion with labor unions of the essence. There is a growing interest by the unions in health protection. Undoubtedly, such concern is or will be a factor in contract negotiations.

However, the representative from DuPont advised that their relationships with the local unions dictated that their procedure would be to deal directly with the employees and then inform the unions.

The same procedure would largely be followed in the rubber industry where, at Goodyear alone, there are 15 plants involved. General Motors, on the other hand, would seem to prefer a more direct approach to the union.

3. Peer Review

The question arose as to whether AACI could peer review itself. The general consensus was that it could, especially for science and technical review. However, there are several levels to consider, as follows:

- a. Technical
- b. Political Policy or creditability review
- c. Duplication

4. AACI Capability

A profile of centers should be used as a basis of resource information. Approval for use of such material must be obtained from the NCI and each respective institution.

5. Approaches

a. One procedure for conducting the research programs would be to utilize the task force approach, i.e., a lead institution with a program director, assisted by a committee of experts.

b. It was stated that the AACI is the only group that has the capability and/or creativity for establishing a data base as would be required for such a program.

c. The ORC could serve as the clearing house for industry in that it deals with the American companies that are most concerned with the issues.

Meeting of the Representatives
AACI and ORC
July 20, 1977
Page 4

CONCLUSION

1. It was agreed that there appears to be good reasons that the ORC and the AACI could serve as the basis for the development of studies of mutual benefit in the area of environmental carcinogenesis.

2. There would have to be drafted a definition of the critical issues to serve as a basis for further discussion. For the ORC or industry, problems requiring resolution should be defined. Among these were:

- a. Carcinogenicity of compounds or agents
- b. Data base
- c. Detection

For the AACI, likewise, a corollary definition of issues should be developed in terms of:

- a. What needs to be done, in terms of acquisition of knowledge about the diseases of cancer, or,
- b. What areas of investigation or control are not being adequately pursued, that by so doing would be of value to the cancer problem.

3. It was agreed that both parties would pursue these matters and that a future meeting would be held in the fall of 1977. Meanwhile, in September 1977, ORC would convene a meeting of 26 health directors to study these critical issues.

Respectfully submitted,

Don

H. Donald Putney

lmc.

THE UNIVERSITY OF TEXAS SYSTEM
CANCER CENTER

MEMORANDUM

DATE: 9-12-77

Dr. Charles Shaw

TO: Mr. P. A. Leon

FROM: JoAnne Hale

OFFICE OF THE PRESIDENT

MESSAGE:

✓
Doctor Clark asked that the attached memo be sent to you for your review and he would appreciate your responding to Doctor Shingleton. Thank you for your cooperation

cc: CJackson

*No Response
as of 11/6*



association of american cancer institutes

10.2
Dr. Shaul
H.L.
10.29
action

OFFICERS

President
William W. Shingleton, M.D.
Duke Comprehensive Cancer
Center
Durham, North Carolina

Vice President
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Comprehensive Cancer
Center for the State of
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Miami, Florida

Secretary-Treasurer
Edwin A. Mirand, Ph.D.,
D.Sc.
Roswell Park Memorial
Institute
Buffalo, New York

MEMORANDUM

TO: Center Directors
FROM: William W. Shingleton, M. D.
DATE: August 22, 1977
RE: AACI interaction with industry in environmental carcinogenesis

Further discussions have taken place with Mr. Wayne Brooks of Organization Resources Counselors, Inc. in Washington, D. C., an organization which represents approximately 60 large industrial concerns. We are in the process of submitting a list of research projects in environmental carcinogenesis which cancer centers can undertake in the interest of industry.

BOARD OF DIRECTORS

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Houston, Texas

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Camden, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

I would like for each of you to please inform me of the areas of research related to cancer in industry in which your centers are interested. This can include epidemiological studies, basic or clinical studies and other related studies. I would appreciate hearing from you at your earliest convenience. Thanks and best wishes.

Bill

GTS - 3814
Duke University Medical Center
DURHAM, NORTH CAROLINA
27710

R. LEE CLARK, M. D.

Carmault Jackson, M. D. in charge of our Extramural program (including "blood" relations) is a hematologist .

He could be a fine representative of AACI (as he also is a good negotiator) on the ABC.

RLC

R. LEE CLARK, M. D.

Carmalt Jackson M.D.
in Charge of our Extra-
Mural program -
(including "blood ~~press~~
relations) is a haematologist
-oncologist.

He could be a fine
rep. of AACI - as
he also is a good negotiator
- on the ABC

R L C

10.2
August 9, 1977

Dr. William Shingleton
President
Association of American Cancer Institutes
Duke Comprehensive Cancer Center
Duke University Medical Center
Durham, North Carolina 27710

Dear Bill:

I have read Nat Berlin's letter asking to be relieved as AACI representative to the American Blood Commission. I believe that his request is in order as we must have a representative who is vitally interested in the problem of blood procurement for the cancer patient and is able to give of his time to ably represent the AACI. The blood needs of the patients undergoing treatment for cancer has now become one of the major uses for blood.

Doctor Berlin also questions our participation in paying dues to the American Blood Commission (ABC). I am firmly convinced that we should be in a position to provide the ABC information relative to our needs as cancer institutes and help solve the impasse which now exists between the American Red Cross and the Association of American Blood Banks. In a vital situation such as this it is understandable that the ABC wishes to obtain some type of operational consensus. There are many things involved, however, we are basically talking about money and territoriality.

In conclusion my own feeling is that the AACI should participate in the solution of the blood procurement problem which is very vital to us. By sending a representative to the ABC we are also in a position to negotiate on our dues to their organization. If you wish, I would be happy to discuss the establishment of a panel from which we could draw a representative who, as mentioned before, is truly interested in the problem and could well represent us at the meetings.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC:jh

From the Desk of . . .

William W. Shingleton, M.D.

Lee:

I would appreciate your thoughts regarding the American Blood Commission and the value of our participation in this organization. Note the enclosed. Thanks.

Bill

M. D. ANDERSON HOSPITAL
RECEIVED
OFFICE OF THE PRESIDENT

JUL 11 1977

THE UNIVERSITY OF TEXAS

CANCER CENTER
OFFICE OF THE DIRECTOR
WARD MEMORIAL BUILDING
203 E. CHICAGO AVENUE

Dr. William Shingleton
Duke University Comprehensive
Cancer Center
Durham, North Carolina

Dear Bill:

Last year, Al O'Connell
for being the liaison member of the
Association of American Cancer Centers
demands on my time have been so great
fully my responsibilities at the University
also written separately. I have not
have charged our Association with the
put that on the agenda.

I would also like to list
responsibilities to the
AACI. I find that I need
I would like to do, and

NIB:ac

NORTHWESTERN UNIVERSITY

CHICAGO, ILLINOIS 60611

CANCER CENTER
OFFICE OF THE DIRECTOR
WARD MEMORIAL BUILDING
203 E. CHICAGO AVENUE

June 15, 1977

*Hold for
Based on info.*

Dr. William Shingleton
Duke University Comprehensive
Cancer Center
Durham, North Carolina

Dear Bill:

Last year, Al Owens asked me if I would take the responsibility for being the liason member for the American Blood Commission from the Association of American Cancer Institutes. I regret very much that the demands on my time have been such that I have not been able to discharge fully my responsibilities to the American Blood Commission. I have also written separately to Ed Mirand suggesting that the dues that they have charged our Association appear to be large, and suggested that he put that on the agenda, whether we should participate.

I would also like, at this time, to ask you to be relieved of my responsibilities to the American Blood Commission in representing the AACI. I find that I no longer have the time to do many of the things I would like to do, and must begin to restrict my time.

Very sincerely yours,

Nat
Nathaniel T. Berlin, M.D.
Director, Cancer Center

NIB:ac

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and
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jh
6/1
6

THE UNIVERSITY OF TEXAS SYSTEM
CANCER CENTER

MEMORANDUM

DATE: 6-14-77

TO: Dr. Robert C. Hickey

FROM: Donna Hale
OFFICE OF THE PRESIDENT

MESSAGE:

Doctor Clark has not seen the attached correspondence. Would you be willing to review and respond for him? I am sure he would greatly appreciate it. If you need my help in any way please let me know.

Thank you,

5-5; Donna said RCH has not
replied to date
5/13
PSF(1-117)

Birth
This is an item we received during RLC's absence for Surgery - I referred to RCH - who lost and sent them another copy. I called today and Donna said RCH was not going to do anything on it that he had talked with Shingleton several times and was going to the AACI meeting - I told her this wasn't regarding that meeting. She said RCH did ~~nothing~~ nothing.

jh
6/14/77

6-14-77 file. We cannot make them respond. BRW

jh -
file
10.2

6-14-77



OFFICERS

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D.Sc.
Roswell Park Memorial
Institute
Buffalo, New York

MEMORANDUM

TO: Cancer Center Directors
FROM: William W. Shingleton, M. D., President
DATE: April, 1977
RE: Report of the Intrainstitute Committee on Cancer Centers

The Board of Directors of the AACI have approved the action of submitting a specific organizational response to the report of the Intrainstitute Committee on Cancer Centers. A copy of the report is enclosed, with comments made by Dr. Newell in the margins. In order for our response to be compiled, we are requesting all Center directors to review the report and then forward your comments to me. Dr. Owens, Dr. Zubrod and I will then prepare recommendations to submit to Dr. Newell and the National Cancer Advisory Board Subcommittee on Centers.

It would be most appreciated if your review could be sent to me at your earliest convenience, and if possible, no later than May 10. Thank you very much for your assistance in this crucial area.

BOARD OF DIRECTORS

Albert H. Owens, Jr., M.D.
— Chairman
Baltimore, Maryland

Oliver H. Beahrs, M.D.
Rochester, Minnesota

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Houston, Texas

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Seattle, Washington

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Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

5/3 - Called Dr. Shingleton & told Allen we would have a delay but would forward comments when received (see conversation with Donna)

6/14 Called Donna & she said he does not plan to respond.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20814

DEC 30 1976

December 28, 1976

NATIONAL CANCER INSTITUTE

*File
AHC I*

G. Denman Hammond, M.D.
Associate Dean
School of Medicine
Director, Comprehensive Cancer Center
University of Southern California
Los Angeles, California 90033

Dear Denny:

Enclosed is a copy of a memorandum from Tom King to me in which he transmits the report of the Intrainstitute Committee on Cancer Centers. You will recall that an unofficial version of this report was discussed at the last meeting of the NCAB subcommittee. Please note Tom's cover memorandum and also my comments in the margin. I know you have thoughts of your own about this, and I look forward to having them either at the next NCAB meeting or before.

I am also sending Jonathan Rhoads a copy as chairman of the NCAB.

With best regards for the New Year.

Sincerely,

Guy R. Newell, M.D.
Acting Director
National Cancer Program

Enclosure

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Acting Director, NCI

DATE: December 1, 1976

FROM : Director, Division of Cancer Research
Resources and Centers, NCI

SUBJECT: Report of the Intrainstitute Committee for Cancer Centers

12/1
cc: OD Staff } fyi

I am pleased to forward to you the report of the Intrainstitute Committee for Cancer Centers. Having met 10 times since June 30, the Committee completes its charge with the submission of the attached report to the Director. The continued coordination of the Cancer Centers Program with all other NCI center-related programs is the responsibility of the Associate Director for the Cancer Centers Program, 3.2.1 (p. 9). During the course of its deliberations, the Committee focused on the following questions:

1. What is a Cancer Center?
2. Is the Cancer Centers Program a "program," a "resource," or a "funding mechanism?"
3. What are the responsibilities of NCI and cancer centers to each other?
4. Where should a cancer center be located and what is its regional influence?
5. What should be the role of the NCI Cancer Centers Program management and what are the organizational parameters within which it operates?

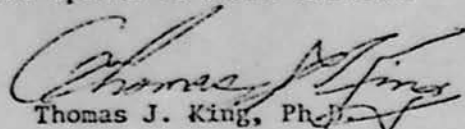
In submitting the report, I would like to call your attention to certain recommendations which could cause problems and which merit your critical attention.

1. 1.1 (p. 1) and 3.1.1 (p. 7) - The inclusion of a cancer center support (core) grant (CCSG) in NCI's programmatic definition of a cancer center is not meant to equate a mechanism of support with an institution that is considered to be a cancer center. It is simply a matter of fact that the characteristics which make for "centerness" are embodied in the criteria that permit such institutions to qualify for a cancer center support grant.

2. 1.3 (p. 2) and 3.3.1 (p. 10) - This implies that NCI core grant support will terminate or be sharply curtailed after 10 years. I do not believe this is a good policy for NCI. Such an attitude on the part of NCI would lead the scientific community to doubt the existence of a real commitment to the centers program.

3. 1.5 (p. 4) and 3.5.1 (p. 16) - This recommends that the Diagnosis and Treatment Branch be separated from the Associate Director for the Cancer Centers Program. This recommendation causes a number of problems within DCRRC. The basis for this recommendation was to enable the centers program (core and exploratory grants) to have a line item budget. This can be accomplished without an organizational change. I am not prepared to follow through on this recommendation before making a thorough evaluation of the entire structure of the Division of Cancer Research Resources and Centers.

I would like to commend all members of the Committee for their willingness to work on this task and for their dedication and devotion. I believe the overall excellence of the report speaks to their efforts.


Thomas J. King, Ph.D.

Attachment

REPORT
of the
INTRA-INSTITUTE COMMITTEE FOR CANCER CENTERS
to the
DIRECTOR
NATIONAL CANCER PROGRAM/NATIONAL CANCER INSTITUTE

November 15, 1976

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1. EXECUTIVE SUMMARY: RECOMMENDATIONS

1.1 What is a Cancer Center?

--That the following definition be adopted: For National Cancer Institute (NCI) programmatic purposes, a cancer center is any organizational unit that consolidates and focuses cancer-related activities in a single administrative and programmatic structure and is supported by a cancer center support (core) grant (CCSG). All recipients of this type grant are expected to meet the following criteria:

1. established programs of high quality basic and/or clinical research;

2. a defined operational plan to coordinate cancer-related activities;

3. a qualified director of the cancer center program serving on a full-time or significant part-time basis;

4. sufficient autonomy to fulfill its program responsibilities; the cancer center should be recognized as a major element within the organizational structure of the parent institution of which it is a part;

5. adequate physical facilities to house the center's activities and to promote collaboration among its constituent programs [to ensure successful operation of the cancer center];

6. an [established mechanism to ensure] adequate planning and evaluation of the cancer center's programs.

1.1.1 Types of Cancer Centers

--That cancer centers be categorized as follows:

OK { (1) comprehensive, where long-term multidisciplinary programs are conducted and meet the 10 characteristics established by the National Cancer Advisory Board (NCAB); (2) clinical, where clinical research and demonstration projects are available and where "bench" or "basic" research may or may not be done, and (3) [non-clinical] where the emphasis is on "bench" or "basic" research. (These three categories are not intended to imply three different types of CCSGs. All cancer centers will be supported by, as far as possible, a single CCSG award.)

agree { --That, except for comprehensive cancer centers, NCI will not officially recognize or designate cancer centers of any other type.

?
distinct, discrete?
physical facilities alone doesn't do this

OK
don't like the negative connotation. Can't we call it something positive.

1.2 Is the Cancer Centers Program a "Program," a "Resource," or a "Funding Mechanism?"

--That the Cancer Centers Program be considered a "program" by NIH definition to implement the necessary coordination, procedural, information, and evaluation functions that will make it a valuable and useful resource to other elements of the National Cancer Program.

--That the Cancer Centers Program be considered a resource as is any other program or project eligible for NCI funds.

--That the Cancer Centers Program prepare a plan with goals, objectives, and mechanisms to evaluate and implement it.

1.3 What are the Responsibilities of NCI and Cancer Centers to Each Other?

--That NCI, through CCSCs, be responsible for creating a climate for institutional stability. Present support is limited by law (National Cancer Act) to three-years. This time constraint consumes much cancer center staff effort in application preparation and submission, and NCI staff time in review. This problem would be alleviated by lengthening the CCSC support from three to five years. Although NCI assumes responsibility for providing institutional stability through CCSC awards, limited resources necessitate that cancer centers be encouraged to gradually seek other funding sources for sustained core support. This implies that NCI cancer center support through CCSCs gradually decreases as the cancer center becomes more established and stable.

--That institutions who foster the development of cancer centers share with NCI the responsibility for cancer center stability. To achieve this, the fostering institution should make a long-term commitment of resources, space, services, and personnel, and should make every attempt to achieve self-sustaining stability for the cancer center over a 10-year period.

--That NCI not expect all cancer centers to be cast in the same mold. Each should strive to meet specific conditions of clinical excellence and regional involvement appropriate to the individual cancer center capabilities and its setting. This implies the importance of identified goals and objectives for individual cancer centers and the need for planning in each cancer center to achieve its objectives within and as a part of the NCP.

--That cancer centers cannot be and should not be favored resources or receive preferential funding treatment in competing for research program resources. They should be subject to the same peer review process as other applicants competing for NCI support funds.

--Regarding technical capability, that cancer centers be responsible for developing and maintaining scientific excellence in their research capabilities and results. This implies that cancer

There may be times when NCI asks centers to do something (like data collection) where we should provide differential resources. Certainly no preferential funding for research dollars.

implies a separate plan. Don't think you mean to.

Agree

disagree

if anything needs long term commitment its core support.

disagree

Agree

agree in general but

"scientific excellence" to "research resources" to
"development efforts." Needs clarification.

3

centers should cooperate with and utilize quality research resources that already exist in their regions and concentrate development efforts on needed capabilities not presently available to them.

--That cancer centers, as a program resource, be responsive to specific NCI program needs in areas where they have demonstrated qualifications and capabilities. Both cancer centers and NCI should recognize the need for flexibility of choice with regard to the balance of activities each cancer center is expected to achieve.

--That NCI and cancer centers have a joint responsibility to catalogue the resources and capabilities of each cancer center to provide a complete index of the capabilities of cancer centers as a resource to all participants in the National Cancer Program. Cancer centers should participate with NCI in developing an individual institutional profile of the center's activities and potential to be as current as possible to serve as an information base for the Cancer Centers Program.

--That NCI is responsible to develop and state objectives for the Cancer Centers Program. NCI also has responsibility to inform cancer centers of [limitations to future support] and to work with each cancer center to achieve a realistic balance so that both cancer center and NCI can be [assured of relatively stable maintenance of the cancer center capability as a resource]. With regard to new cancer centers, NCI has a responsibility to examine its obligations to currently funded cancer centers in light of National Cancer Program needs and tailor the development of new cancer center capabilities to these needs. NCI also has a responsibility to monitor the performance and capabilities of cancer centers periodically and to inform the cancer centers of the results of these findings.

1.4 Where should a Cancer Center be Located and What is its Regional Influence?

--That a primary goal of the NCI Cancer Centers Program be to ensure that there are cancer centers of excellence for research in clinical oncology for cancer patients and physicians within the U.S. That NCI comprehensive and clinical cancer centers contribute to meeting this need. Both types of cancer centers should be included in "appropriate geographic distribution."

--That NCI, through the Cancer Centers Program, complete its survey of the effectiveness of existing cancer centers' regional influence.

--That, at the present time, cancer centers not be considered focal points for ALL cancer activities in their "regions." but be encouraged to coordinate activities to maximize utilization of resources and avoid undesirable duplication.

not carried thru into the recommendations

Isn't this out of place?

4

[--That no more comprehensive cancer centers be recognized unless they currently have the resources requisite for recognition as comprehensive as determined by the NCAB.]

1.5 What should be the Role of the NCI Cancer Centers Program Management and What are the Organizational Parameters within which it Operates?

OK [--That the Cancer Centers Program management remain in the Division of Cancer Research Resources and Centers, and be headed by an Associate Director having the authority to organize and staff the Program to carry out his responsibilities.

Internal
Review
over your
cancer
memo [--That the Associate Director for the Cancer Centers Program be responsible for management and administration of only CCSCs and the use of exploratory grants as they relate to the development of cancer centers. The management and administration of the Diagnosis and Treatment Branch and the Research Facilities Branch should not be the responsibility of the Associate Director for the Cancer Centers Program.

Agree
good [--That the NCI Cancer Centers Program management be a source of information and program guidance, therefore serving a triage function to assist cancer centers with contacts and information from NCI concerning other aspects and activities of the National Cancer Program.

2. BACKGROUND

2.1 History of the Centers Program

In 1959, NIH developed an extramural centers program patterned on the concept of the Clinical Center at NIH. Grants were offered to provide costs of renovating a discrete bed unit with a core laboratory for research procedures, a laboratory for research procedures, and a laboratory for the center director. In addition, the grants funded the total cost of hospitalization and other necessary costs of operating the unit as a clinical research facility. The cost of doing research in the unit was not provided by these center grants; rather such costs were to be obtained by means of research project grants or program project grants. By 1961, several of the categorical institutes, including NCI, began providing grant support for clinical research centers. In the case of NCI, the centers grants were designed to provide support for outpatient facilities as well as inpatient and radiation therapy programs. In addition, these cancer center grants combined support for both the clinical resource and the research associated with the facility into one grant application. These early cancer center grants supported primarily chemotherapy research centers and radiation therapy centers and emphasized multidisciplinary activities, i.e., clinical chemotherapy with related pharmacology and biochemistry or radiation therapy with related radiation biology and radiation physics, etc. Another objective of the centers grant program in the early 1960's was to enlarge the scope of existing cancer institutes. To this end, a clinical research bed unit was established at the Institute for Cancer Research and a similar unit was set up at the Detroit Institute for Cancer Research. Prior to this time, both of these institutes had been engaged solely in basic cancer research. Similarly, at the Ellis Fischel Cancer Hospital, a pharmacology and biochemistry laboratory was created to expand activities into laboratory research from a strictly clinical program. In 1966, with the passage of the Regional Medical Programs Act, the NCI budget was increased by \$800,000 to support planning grants. These grants provided institutions with the means to develop cancer center programs and accelerated the creation of multidisciplinary cancer research centers. At the time of the signing into law of the National Cancer Act (1971), there were some 38 institutions which had clinical research center grants. In May 1972, the NCAB interpreted Section 403A of the Act as requiring that NCI establish 15 new comprehensive cancer centers. NCI staff was requested to develop criteria for such cancer centers. Originally the staff presented eight criteria which were accepted and the Board added two more, making a total of 10. It is of some interest that, of the 18 comprehensive cancer centers which have been recognized by NCI, all but one (Ohio State University), had one or more clinical research center grants, program project grants, or planning grants well before the passage of the National Cancer Act.

2.2 Scope and Purpose of the NCI Intrainstitute Committee for Cancer Centers

The scope and purpose of the Intrainstitute Committee for Cancer Centers was to promote a better understanding of the Cancer Centers Program activities and to achieve a better relationship with all NCI programs. This Committee considered areas of concern throughout NCI which involved the Cancer Centers Program. Issues of interest to other NCI programs were also discussed. The Committee was charged to prepare a report for the Director, National Cancer Program/National Cancer Institute.

Many issues were identified and discussed by the Committee in the framework of the following questions:

- What is a cancer center?
- Is the Cancer Centers Program a "program," a "resource," or a "funding mechanism?"
- What are the responsibilities of NCI and cancer centers to each other?
- Where should a cancer center be located and what is its regional influence?
- What should be the role of the NCI Cancer Centers Program management and what are the organizational parameters within which it operates?

3. ISSUES AND RECOMMENDATIONS

3.1 What is a Cancer Center?

The lack of definition of a cancer center has led to considerable confusion in NCI as well as in the outside scientific and lay communities. The definition most widely accepted by both members of NCI and the scientific community is that a cancer center is any entity that is funded from the "cancer centers program budget," which is perceived to include all CCSGs, program project grants, and exploratory grants. Use of this definition would indicate that there were approximately 189 "cancer centers" funded by NCI in FY-75. Some individuals within DHEW, NIH, OMB, GAO, and the scientific community have assumed that the budget for the Cancer Centers Program supports the total activities of a "center," such as planning, CCSG support, construction, research program support, and educational and demonstration program support.

Such perceptions do not distinguish between the costs of developing and maintaining a cancer center (CCSG) and the costs of supporting component programs of that cancer center (e.g., research, education, and demonstration). Therefore, any interpretation or definition of the cancer centers concept based on total budget will lead to an erroneous conclusion as to the actual cost of establishing and maintaining cancer centers. Clearly the total output and impact of a cancer center relates to its total program and, therefore, its total budget. However, the cost of establishing and maintaining a cancer center relates only to the support of its "core" activities, some planning funds, and in some cases construction support. The definition of a cancer center should take this into account. Also, it is imperative that a more clear-cut and supportable definition of a cancer center be developed which can be used by NCI staff and the scientific and lay communities and be understood by all.

Key point

agree

3.1.1 Recommendations

—That the following definition be adopted: For NCI programmatic purposes, a cancer center is any organizational unit that consolidates and focuses cancer-related activities in a single administrative and programmatic structure and is supported by a CCSG. All recipients of this type grant are expected to meet the following criteria:

1. established programs of high quality basic and/or clinical research;
2. a defined operational plan to coordinate cancer-related activities;

3. a qualified director of the cancer center program serving on a full-time or significant part-time basis;

4. sufficient autonomy to fulfill its program responsibilities; the cancer center should be recognized as a major element within the organizational structure of the parent institution of which it is a part;

5. adequate physical facilities to house the center's activities and to promote collaboration among its constituent programs to ensure successful operation of the cancer center;

6. an established mechanism to ensure adequate planning and evaluation of the cancer center's programs.

--That cancer centers be categorized as follows:

(1) comprehensive, where long-term multidisciplinary programs are conducted and meet the 10 characteristics established by the NCAB; (2) clinical, where clinical research and demonstration projects are available and where "bench" or "basic" research may or may not be done, and (3) non-clinical, where the emphasis is on "bench" or "basic" research. (These three categories are not intended to imply three different types of CCSGs. All cancer centers will be supported by, as far as possible, a single CCSG award.)

--That, except for comprehensive cancer centers, NCI will not officially recognize or designate cancer centers of any other type.

3.2 Is the Cancer Centers Program a "Program, a "Resource," or a "Funding Mechanism?"

NIH developed the following definition of a program which was utilized by NCI in August 1974 in the National Cancer Program Operational Plan:

A coherent assembly of plans, projected activities, and supporting resources - contained within an administrative management framework of some kind - to implement an agency's mission or some specific problem-related aspect of that mission.

A program should have one or more of the following attributes: (1) clearly defined and specified objectives or purposes which are discrete and acceptable as an end to be obtained; (2) separate item identification in the annual budgetary process;

(3) distinct organizational status by virtue of its magnitude and significance; (4) activities where there is a clear-cut process of managing and directing a given set of operations, sum of money, or staff to accomplish specified objectives or purposes.

A review of many other definitions, including the NIH definition, shows that any organizational activity to be considered a program must contain certain key elements which are: (1) plan with clearly defined objectives; (2) separate budgetary identification; (3) distinct organizational status; and (4) clear-cut process of managing and directing to accomplish specified objectives.

The concept of the Cancer Centers Program as a resource is not in conflict with it being a program. "Programs" are or should be implemented through a variety of "funding mechanisms," i.e., contracts, individual investigator grants, program project grants, CCSC grants, etc., depending upon the scientific program needs. An important factor examined by site visitors is the quality, number, and diversity of support the cancer center obtains in a competitive fashion. This would, therefore, imply that more than one type of funding mechanism is associated with a cancer center.

3.2.1 Recommendations

--That the Cancer Centers Program be considered a "program" by NIH definition to implement the necessary coordination, procedural, information, and evaluation functions that will make it a valuable and useful resource to other elements of the National Cancer Program.

--That the Cancer Centers Program be considered a resource as is any other program or project eligible for NCI funds.

--That the Cancer Centers Program prepare a plan with goals, objectives, and mechanisms to evaluate and implement it.

3.3 What are the Responsibilities of NCI and Cancer Centers to Each Other?

At the present time, of the institutions receiving CCSCs, 18 have been recognized by NCI as comprehensive cancer centers. The remainder have diverse capabilities, some in basic laboratory research, some in multidisciplinary clinical research; some have both laboratory and clinical research capabilities, while others have specialized clinical research capabilities, such as radiation oncology. Each cancer center has a combination of facilities, staff, resources, and capabilities unique to that cancer center.

Collectively, all the above types of cancer centers are a national resource for the accomplishment of the scientific effort needed to achieve the objectives of the National Cancer Program. Characteristics particularly important (although not necessarily unique) to cancer centers in this role as a national resource include the following:

1. Cancer centers can maintain a critical mass of staff with a variety of clinical and basic skills whose abilities can be applied to specific cancer research and application projects, and develop facilities and supporting services to facilitate multidisciplinary research and training;
2. Cancer centers have a primary commitment to the single disease, cancer, and to the overall cancer problem. This commitment is an opportunity for cancer centers to serve as a focal point in the community for aspects of the cancer problem. This makes them a valuable resource for professional training, public education, demonstration of research results, and more rapid transfer of research knowledge of patient care application.

These characteristics outline the value of cancer centers as a resource to the National Cancer Program. They also suggest responsibilities on the part of each individual cancer center and NCI toward all cancer centers.

NCI is directed by law and committed traditionally to supporting the capability of cancer centers to conduct multidisciplinary basic and clinical research, demonstration of research results, professional education, etc. CCSG support has become the primary mechanism by which NCI fulfills its commitment to cancer centers.

3.3.1 Recommendations

--That NCI, through CCSGs, be responsible for creating a climate for institutional stability. Present support is limited by law (National Cancer Act) to three-years. This time constraint consumes much cancer center staff effort in application preparation and submission, and NCI staff time in review. This problem would be alleviated by lengthening the CCSG support from three to five years. Although NCI assumes responsibility for providing institutional stability through CCSG awards, limited resources necessitate that cancer centers be encouraged to gradually seek other funding sources for sustained core support. This implies that NCI cancer center support through CCSGs gradually decreases as the cancer center becomes more established and stable.

--That institutions who foster the development of cancer centers share with NCI the responsibility for cancer center stability. To achieve this, the fostering institution should make a long-term commitment of resources, space, services, and personnel, and should make every attempt to achieve self-sustaining stability for the cancer center over a 10-year period.

--That NCI not expect all cancer centers to be cast in the same mold. Each should strive to meet specific conditions of clinical excellence and regional involvement appropriate to the individual cancer center capabilities and its setting. This implies the importance of identified goals and objectives for individual cancer centers and the need for planning in each cancer center to achieve its objectives.

--That cancer centers cannot be and should not be favored resources or receive preferential funding treatment in competing for program resources. They should be subject to the same peer review process as other applicants competing for NCI support funds.

--Regarding technical capability, that cancer centers be responsible for developing and maintaining scientific excellence in their research capabilities and results. This implies that cancer centers should cooperate with and utilize quality research resources that already exist in their regions and concentrate development efforts on needed capabilities not presently available to them.

--That cancer centers, as a program resource, be responsive to specific NCI program needs in areas where they have demonstrated qualifications and capabilities. Both cancer centers and NCI should recognize the need for flexibility of choice with regard to the balance of activities each cancer center is expected to achieve.

--That NCI and cancer centers have a joint responsibility to catalogue the resources and capabilities of each cancer center to provide a complete index of the capabilities of cancer centers as a resource to all participants in the National Cancer Program. Cancer centers should participate with NCI in developing an individual institutional profile of the center's activities and potential to be as current as possible to serve as an information base for the Cancer Centers Program.

--That NCI is responsible to develop and state objectives for the Cancer Centers Program. NCI also has responsibility to inform cancer centers of limitations to future support and to work with each cancer center to achieve a realistic balance so that both the cancer center and NCI can be assured of relatively stable maintenance of the

cancer center capability as a resource. With regard to new cancer centers, NCI has a responsibility to examine its obligations to currently funded cancer centers in light of National Cancer Program needs and tailor the development of new cancer center capabilities to these needs. NCI also has a responsibility to monitor the performance and capabilities of cancer centers periodically and to inform the cancer centers of the results of these findings.

3.4 Where should a Cancer Center be Located and What is its Regional Influence?

There is no policy within NCI delineating the regional influence of a cancer center whether it is comprehensive or not. This lack of definition of regional influence has led to confusion. Examples of this are that one comprehensive cancer center feels that it is responsible for an entire State, whereas another comprehensive cancer center feels responsible for a small segment of a city. The confusion carries over into NCI in that regional influence has been defined in many ways, such as: (1) patients should not have to stay overnight in order to receive treatment at a cancer center, (2) no one should be more than "X" miles from a cancer center, and (3) a cancer center is responsible for as large an area as it "can handle."

At a recent meeting of cancer center directors, it was suggested that a comprehensive cancer center should have sign-off authority or at least comment authority on any and all grants and contracts going to NCI from its "region." This "region" was to be determined by the particular cancer center.

The issue of regional influence of cancer centers appears to have arisen in stages. The Yarborough Committee report called for creation of "... additional cancer centers in different parts of the country ...," and said they "... should have appropriate geographic distribution and ... be created where a nucleus of ... personnel already exists and preferably where a university or a medical school affiliation exists or is planned" (92-659, p. 31). It further states "... new centers should not be created where there would be a dilution ... of existing centers" The panel report made clear that the creation of cancer centers "does not mean that the (NCP) is to undertake general responsibility for care and treatment of cancer patients" (92-659, p. 32). Regarding coordination, the Yarborough panel said:

"The ... centers should ... serve as administrative coordinators of those programs which require regional coordination. (They) should support and assist clinics and community medical centers in their own geographic areas in order to assure the widespread use of the best available methods."

Very good statement

The National Cancer Act of 1971 itself does not mention location or coordination, but the report accompanying the House bill does. Since the language of the final law is from the House bill, the report is guiding. The report (92-659, p. 25) states:

"The Committee feels that existing cancer centers should be strengthened and additional ... centers in different parts of the country should be created. These new centers should have appropriate geographic distribution and should, wherever possible, be created where a nucleus of scientific, professional, and managerial personnel already exists.

Cancer Centers can play a major role ... by ... (5) serving as focal points for testing and evaluating outputs of the research and development efforts These functions can be carried out by specialized as well as comprehensive centers."

Agree

The term "appropriate geographic distribution" then needed interpretation. Initial selections of comprehensive cancer centers were natural and fairly easy since they were made at institutions of longstanding undisputed reputation. Coincidentally, they were fairly widely dispersed geographically as well. In the second round of selections, a conscious effort was made to increase geographic coverage. At that point, three factors became apparent:

1. Concentration on quality of pre-existing institutions as the prime selection factor would result in geographic clustering, likely including even more than one center in a given city,
2. Some major parts of the country seemed to lack even the potential for developing a comprehensive cancer center,
3. In the National Cancer Act of 1971, there was no clear rationale for the number 15, either as a target or as a limit.

The General Accounting Office initiated a study which was completed on March 15, 1976, entitled Comprehensive Cancer Centers: Their Locations and Role in Demonstration. This report recommended that HGI should:

"--Decide on the specific factors that will be used to determine locations of comprehensive cancer centers, balancing the need for geographic distribution with other factors.

--Report to the appropriate congressional committees on the effect other factors will have on locations of centers and the feasibility of achieving an appropriate geographic distribution.

--Clarify the role of the comprehensive center as a focal point for demonstration programs, including establishing criteria for determining when the centers can act effectively as focal points."

It should be realized that this GAO report addressed itself only to comprehensive cancer centers. This report has generated a great deal of concern within NCI as to how best to address the issues raised as to location of a cancer center and the regional influence for each cancer center.

In all of these reports and testimony given before Congress, it appears that the "real world" attitude of where a cancer center may be located has been lost. In reality, a cancer center is going to exist where there is a critical mass of physicians, scientists, patients, referral patterns, appropriate local and regional political circumstances, where the cost of such an endeavor is acceptable, and when an organizational entity is ready to mount the effort.

NCI has developed a policy that "centers should have appropriate geographical distribution to ensure maximum benefits ... accrue to the largest possible fraction of the U.S." With respect to cancer center functions in basic research, the appropriate geographic distribution would seem to be in locations where basic research can be carried out; i.e., where there is a critical mass of basic research scientists and proper laboratories. It would not materially increase the benefits to the public to distribute basic research centers equally across the nation; such a distribution might even be inhibitory to progress. On the other hand, the public does have an interest in the geographic availability of institutions carrying out clinical research where the newest advances in clinical oncology are available. The geographic mandate that Congress placed upon cancer centers is interpreted by NCI staff to apply only to clinical cancer centers. The language of the National Cancer Act of 1971 refers to "new centers for clinical research, training, and demonstration of advanced diagnostic treatment methods." One must conclude, therefore, that geographic distribution should be a consideration only in the award of CCSGs for clinical cancer centers and not for non-clinical cancer centers. Geographic distribution of comprehensive cancer centers is important only insofar as they fulfill the clinical research function.

*Good
Statement*

3.4.1 Recommendations

--That a primary goal of the NCI Cancer Centers Program be to ensure that there are cancer centers of excellence for research in clinical oncology for cancer patients and physicians within the U.S. That NCI comprehensive and clinical cancer centers contribute to meeting this need. Both types of cancer centers should be included in "appropriate geographic distribution."

--That NCI, through the Cancer Centers Program, complete its survey of the effectiveness of existing cancer centers' regional influence.

--That, at the present time, cancer centers not be considered focal points for ALL cancer activities in their "regions."

--That no more comprehensive cancer centers be recognized unless they currently have the resources requisite for recognition as comprehensive as determined by the NCAB.

3.5 What should be the Role of the NCI Cancer Centers Program Management and What are the Organizational Parameters within which it Operates?

The present organizational structure of the Cancer Centers Program is within the Division of Cancer Research Resources and Centers under the Associate Director for the Centers and Treatment Program. The Office of the Associate Director for the Centers and Treatment Program includes: (1) the Centers Branch - administration and management of CCSG and exploratory grants; (2) the Research Facilities Branch - administration and management of construction grants; and (3) the Diagnosis and Treatment Branch - administration and management of clinical program project grants and certain clinical research grants.

An evaluation effort during 1975-76 conducted by the Centers and Treatment Program, DCRPC, raised a number of issues regarding the internal administration and organizational placement of the Program. During the evaluation process, 35 NCI senior staff were interviewed as to their views regarding the Centers and Treatment Program. Staff members interviewed included the NCI Director, the Associate Directors in the OD/NCI and selected Deputy Directors, Associate Directors, and Branch Chiefs. The majority of the comments made during these interviews (51.3% of 119) fall into the category of "NCI administration/management." Of this 51.3%, a large majority of the comments focused on the "internal administration and organization."

These comments suggested the following five possible organizational options:

1. The Cancer Centers Program location and organization could remain unchanged.
2. The Cancer Centers Program location could remain where it is and the Diagnosis and Treatment Branch be moved.
3. The Cancer Centers Program could be moved to another Division (DCT/DCCR).
4. A separate resource Division could be created including the Cancer Centers Program.
5. The Cancer Centers Program could be moved to the Office of the Director.

3.5.1 Recommendations

--That the Cancer Centers Program management remain in the Division of Cancer Research Resources and Centers and be headed by an Associate Director having the authority to organize and staff the Program to carry out his responsibilities.

--That the Associate Director for the Cancer Centers Program be responsible for management and administration of only COSGs and the use of exploratory grants as they relate to the development of cancer centers. The management and administration of the Diagnosis and Treatment Branch and the Research Facilities Branch should not be the responsibility of the Associate Director for the Cancer Centers Program.

--That the NCI Cancer Centers Program management be a source of information and program guidance, therefore serving a triage function to assist cancer centers with contacts and information from NCI concerning other aspects and activities of the National Cancer Program.

10.2
April 26, 1977

C. Gordon Zubrod, M.D.
Director
Comprehensive Cancer Center
for the State of Florida
P. O. Box 520875, Biscayne Annex
University of Miami
Miami, Florida 33134

Dear Gordon:

Thank you for your letter of March 25. With Doctor Gehan's expertise and valuable input I would prefer that he remain on the committee. I would also like for Dr. Albert Gunn to attend the next meeting with the Food and Drug Administration as a legal advisor and AACI liaison member. Without Doctor Gunn's assistance we would not have made the progress to date with the FDA. Our institution will pay for any travel expenses incurred by Doctor Gunn for this meeting.

Sincerely yours,

R. Lee Clark, M.D.
President

RLC: jh

Dictated by RLC and signed in his absence

bcc: Dr. Gunn

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March 25, 1977

R. Lee Clark, M.D.
President
The University of Texas
System Cancer Center
Texas Medical Center
Houston, Texas 77030

Dear Lee:

It was so nice to meet with you in Atlanta and I thought the meeting of the Board of Directors was informative and productive.

We did speak about Albert Gunn and the possibility of his attending our next meeting with the Food and Drug Administration. I will be happy to consider this, and I think we have two options: One would be that he would be invited as a consultant to a meeting when we are meeting the Food and Drug Administration. I have looked into this after seeing you in Atlanta and I find the procedure under the new contract rather cumbersome and might not be accomplished in time to invite him to the meeting. I therefore would be glad to invite him if you could pay his expenses. The other option would be that he might replace Ed Gehan on the committee and become a permanent member. If you want to nominate him in place of Ed Gehan as representative of M. D. Anderson on the committee, please let me know and I will make this recommendation to Bill Shingleton. I hope Dr. Gunn will be able to come in one way or another.

With warm regards.

Sincerely yours,

C. Gordon Zubrod, M.D.
Director
Comprehensive Cancer Center
for the State of Florida

CGZ:mg

THE UNIVERSITY OF TEXAS SYSTEM
CANCER CENTER

Texas Medical Center Houston, Texas 77025

OFFICE OF THE PRESIDENT

April 19, 1977

Dr. Robert Hickey
Chairman, Task 3, 4, and 5 -
Patient Information System
Association of American Cancer
Institutes
M.D. Anderson Hospital and Tumor
Institute
Houston, Texas 77030

Dear Bob:

I am writing you concerning the recent letter that I received from Dr. John Laszlo, Professor of Medicine at Duke University Medical School which is a follow-up of his discussion on my report to the AACI concerning the activities of the Commission on Cancer of the American College of Surgeons.

Knowing the temper of the climate of the American College of Surgeons concerning "Cancer Programs" and the Cancer Registry Manual which the Commission on Cancer has prepared for distribution to some 750 approved cancer programs, I was pleased to have the opportunity to again chat with you concerning Dr. Laszlo's proposal. I am glad that you feel the proposal should be remanded back to the Board of Directors of the AACI for further evaluation at the June 26-28, 1977, meeting at which time I could be given more explicit instructions as the liaison representative from the AACI re submitting this or any other report to the Commission on Cancer of the American College of Surgeons.

I feel certain that Drs. Shingleton and Owens would certainly go along with this approach. We will be dealing with a more or less monolithic stance on the part of Dr. Andrew Mayer, Assistant Director of the ACS and the Commission on Cancer will have to consider carefully the reasons why any changes should be made in the College of Surgeons Cancer Registry Manual.

I am sending a copy of this note to Drs. Shingleton, Owens, and Mirand asking that this matter be put on the agenda of the Board of Directors meeting in June.

FILM

Dr. Hickey
Page 2
April 19, 1977

I presume we will have the opportunity to discuss the matter with the Board at that time.

Sincerely,

Murray M. Copeland
Murray M. Copeland, M.D.
Vice President
The University Cancer Foundation

MMC/bs

cc: Dr. William Shingleton
Dr. Albert Owens
Dr. R. Lee Clark
Dr. Ed Mirand



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Foundation

Duke University Medical Center
DURHAM, NORTH CAROLINA

DEPARTMENT OF MEDICINE
LANE LABORATORY
HEMATOLOGY RESEARCH

January 12, 1977

Dr. Murray M. Copeland
M.D. Anderson Tumor Institute
Univ. of Texas System Cancer Center
Houston, Texas

Dear Dr. Copeland:

This is in follow-up of our discussion of your report to the Association of American Cancer Institutes in your capacity as liaison member to the Commission on Cancer of the American College of Surgeons. You know we have worked very hard under the direction of Dr. Robert Hickey to come up with a satisfactory minimal data format for all patients with cancer who come to our cancer centers and this has been accepted by the AACI for all of its comprehensive centers and specialized centers. The Association of Community Cancer Centers is also interested in using our format - in preliminary explorations with us. Dr. R. Lee Clark and Dr. Hickey have just spoken to our AACI membership and talked in terms of international cooperation on clinical data, one element of which might well be our minimal data system.

I would like to recommend that you present to the Commission on Cancer of the American College of Surgeons our proposal to use the forms that we have developed instead of the forms that are currently in use. I did serve on a committee at the request of Dr. Mayer and made my feelings on this known in meetings that were held a couple of years ago. As I understand the decision however, was not to adopt our forms and at the same time this forces us to try to get data which both forms require. I know that Dr. Mayer thinks that the differences are trivial but they are important to us. We have been just delighted with two years of work with the new system and we are prepared to help train others if anyone requests. I do think we should not overlook the fact that the cancer centers are enthusiastic now about our new system as opposed to what they have been doing in the past and they will be very valuable resources for the Commission on Cancer in providing guidance and leadership in hospitals throughout the United States. The monitoring that is done on the performance of tumor registries by the Commission on Cancer is valuable but I think the leadership role of cancer centers will be a very positive factor in the years to come.

I am taking the liberty of sending a copy of this letter to Dr. Robert Hickey since he is the Chairman of our AACI Task Force and he may have some suggestions of his own. With kindest regards.

Sincerely,

John
John Laszlo, M.D.
Professor of Medicine

cc: Dr. Robert Hickey

Today's Date

dd-mmm-yy

Accession No.

History No.

Patient's Name

Sex

last

first

middle

maiden

Street Address

Telephone

Birthplace

Lifetime Occupation

City

State

Zip

city/county

Birthdate

County

State / Country

dd-mmm-yy

Soc. Sec. No.

Race

Marital Status

Spouse's first name

Contact Name

Relationship

Contact Address

Telephone

Zip

Primary Physician
or Clinic NamePrimary Physician
or Clinic Address

Telephone

Zip

Duke Physician(s)

Duke Service/Clinic with
Primary Responsibility

Prior History of Cancer (Verbatim)

Date of 1st recognition
of disease by patient
or screening

mmm-yy

Date of 1st physician
contact

mmm-yy

Date of definitive
diagnosis of cancer

mmm-yy

Basis for def. diag.

Biopsy _____

Cytology _____

Other _____

Institution at which
def. diag. made

Address

street

city

Duke Confirmation
Confirmed
Not confirmed
UnavailablePrior treatment of this cancer:
Surgery Immunotherapy
Chemotherapy Endocrine
Radiation None
Radioisotopes

Anatomic Site

ICD - 0

Histologic Type

ICD - 0

CANCER FLOW SHEET

		Initial Workup	Accession No:				Name: Hx.No:	
DATE	DD mm yyyy							
NO CHANGE								
STATUS								
EXTENT								
New Site of Metastasis								
Evidence for Metastasis								
Performance Status		%	%	%	%	%	%	%
TREATMENT PROTOCOL								
Y: yes	#1							
N: no	2							
	3							
	4							
	5							
	6							
	7							
	8							
HOSPITALIZED:								
A: Admission								
D: Discharge								
S: Service								
PHYSICAL EXAM:								
Y: Yes								
N: No								
DATE OF DEATH		PLACE OF DEATH				AUTOPSY		
/ /								
dd mm yy		city state county				yes___ no___		

NOTES:

FLOW SHEET DEFINITION

NO CHANGE: In the x if, on routine follow-up, no aspect of the patient's condition is changed.

STATUS: REM: Alive, no evidence of residual cancer (remission)
 PER: Alive, with evidence of persistent cancer
 REC: Alive, with evidence of recurrence (after remission)
 D/C: Dead, of cancer
 D/O: Dead, other causes
 D/U: Dead, unknown causes
 UN: Unknown (lost to F/U)
 NEW: Alive, untreated cancer

EXTENT: I/S: In situ
 LOC: Localized
 INV: Invasive primary disease
 LXM: Spread to regional lymph nodes
 MET: Metastatic
 DIF: Diffuse disease
 UN: Unknown
 (Stage): Staging, appropriate to specific malignancy

METASTASIS:
 RLN: Regional lymph nodes LI: Liver
 LU: Lung parenchyma PER: Peritoneum
 CNS: Brain BO: Bone
 BM: Bone marrow SK: Skin
 PL: Pleura OT: Other (Describe)

EVIDENCE FOR METASTASIS:
 BI: Biopsy
 SC: Scan of appropriate organ
 XR: X-ray of appropriate organ
 AR: Arteriography
 CYT: Cytology from appropriate site
 LAB: Lab data (hematologic, enzymes, immunologic tests, etc.)
 PE: Physical exam

PERFORMANCE STATUS:
 100% Normal, no complaints; no evidence of disease
 90% Able to carry on normal activity; no major signs or symptoms of disease.
 80% Normal activity with effort; some signs and symptoms of disease
 70% Cares for self; unable to carry on normal activity or do active work.
 60% Requires occasional assistance, but is able to care for most of his needs.
 50% Requires considerable assistance and frequent medical care.
 40% Disabled; requires special care and assistance.
 30% Severely disabled; hospitalization is indicated, although death not imminent.
 20% Very sick; hospitalization necessary; active supportive treatment is necessary.
 10% Moribund, fatal processes progressing rapidly.

PERFORMANCE STATUS (enter after %):
 C If deterioration of status is due to cancer
 O If deterioration of status is not due to cancer

PROTOCOL:
 Y If patient is on a protocol
 N If patient is not on a protocol

HOSPITALIZED: PHYSICAL EXAM SINCE LAST FOLLOW-UP:

A: Admission Date Y: Yes
 B: Discharge Date N: No
 S: Service

TREATMENT PROTOCOL DESCRIPTION:
 S: Surgical IT: Immunotherapy
 C: Chemotherapy E: Endocrine
 R: Radiation OT: Other
 RI: Radioisotopes



THE FOX CHASE CANCER CENTER

10.2.77

7701 BURHOLME AVENUE • PHILADELPHIA, PENNSYLVANIA 19111 • 215/342-1000

TIMOTHY R. TALBOT, JR., M.D.
PRESIDENT

April 11, 1977

Dr. William Shingleton
Director
Duke University Comprehensive
Cancer Center
Duke University Medical Center
Durham, North Carolina 27710

Dear Bill:

I apologize for taking so long to write you. The last ten days seem to have been all-absorbing. In the meantime, I have received Denny Hammond's letter to you dated 31 March. I agree with all that he said. I also agree with Al Owen's letter of 23 March.

As I recall our understanding, you will write Benno, in your capacity as President of AACI, along the following lines or concepts:

1. We wish to give endorsement and encouragement to some of the principal recommendations of the NCI staff committee report as printed in the Cancer Letter - 25 February 1977, pages 4, 5, and 6. Specifically, we believe that the NCI needs to define a Cancer Centers Program including "a program plan which will guide the program to its intended objectives."
2. There needs to be an adequate staff in NCI, preferably within the Division of Cancer Research Resources and Centers, which is not true now, especially when one compares it to other divisions of NCI.
3. It is apparent that existing financial commitments by the Congress to NCI as a whole will not be adequate to ensure that all meritorious programs can be funded. Therefore, the need to establish priorities assumes greater importance than ever; and, as a corollary, the need to establish a sound and rational method for determining budgets for specific programs is of great importance. Many of us have reason to believe that something is awry when, in the face of an increase from \$180,000,000 in 1970 to \$815,000,000 in 1977, approved Core grants may actually be reduced in some cases and will certainly be seriously restricted in most cases. Therefore, we are convinced that unless a Cancer Centers Program is defined as noted above, and unless the budgeting process within NCI gives at least equal weight to the Centers, then the entire Centers Program is doomed to failure.

April 11, 1977

flw

We are also concerned about the influence of "in house" programs versus centers and investigator initiated programs, on the budgetary priorities.

4. I agree with Al Owens that we are now faced with a "Catch 22" -- Core is the major instrument for development and stability of centers but only if Core itself is stable from the NCI budgeting point of view.

5. I agree that excellence as determined by peer review should be the basis upon which individual projects are funded; but, once that process is accepted, then, I fail to see how Core can be reduced without serious consequences.

6. Are there sixty three centers? As noted by Denny, I think that this is really an absurdity! But, I don't know how to lick it. (See last paragraph of page 1 of Denny's letter).

I hope that this is useful to you. I assume that you have received a transcript of our meeting with the President's Cancer Panel. I received a copy and have returned it with minor comments.

Kind regards.

Sincerely yours,

Tim

T. R. Talbot, Jr.

? may I see this?
Rec'd
REC

TRT:pb

cc: R. L. Clark
D. Hammond
A. Owens



association of american cancer institutes

jh
10-20

OFFICERS

President
William W. Shingleton, M.D.
Duke Comprehensive Cancer
Center
Durham, North Carolina

Vice President
C. Gordon Zubrod, M.D.
Comprehensive Cancer
Center for the State of
Florida
Miami, Florida

Secretary-Treasurer
Edwin A. Mirand, Ph.D.,
D.Sc.
Roswell Park Memorial
Institute
Buffalo, New York

April 4, 1977

Dr. R. Lee Clark
President
The University of Texas System Cancer Center
M. D. Anderson Hospital and Tumor Institute
6723 Bertner Avenue
Houston, Texas 77030

Dear Lee:

Thank you for forwarding to me the membership list of the
Oncologic Drugs Advisory Committee. I am referring this to
Gordon Zubrod for his review and recommendation.

With all good wishes, I am

Sincerely yours,

Bill

William W. Shingleton, M. D.
President
Association of American
Cancer Institutes

BOARD OF DIRECTORS

Albert H. Owens, Jr., M.D.
— Chairman
Baltimore, Maryland

Oliver H. Beahrs, M.D.
Rochester, Minnesota

R. Lee Clark, M.D.
Houston, Texas

Lewis L. Coriell, M.D.
Camden, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

WWS:err
cc: Dr. C. Gordon Zubrod

March 25, 1977

Dr. William W. Shingleton
Duke Comprehensive Cancer Center
Duke Hospital
P. O. Box 3814
Durham, North Carolina 27710

Dear Doctor Shingleton:

Attached is a list of the current members of the Oncologic Drugs Advisory Committee. As you will note, the terms of both Doctor Schein and Doctor Sullivan expire in June of this year. Since the AACI adopted a resolution at our January meeting urging that this Advisory Committee of the Food and Drug Administration be given additional authority over the development of investigative new drugs and devices, I thought that the Association might want to recommend physicians to fill the seats being vacated by Doctor Schein and Doctor Sullivan.

Recommendations are now being accepted by Dr. Cyrus Maxwell, Executive Secretary of the Oncologic Drugs Advisory Committee, Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland. Please let me know if I can be of any assistance.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC/jah
encl

Oncologic Drugs Advisory Committee

Chairman:

Shimkin, Michael B., M.D. (1978)
Professor of Community Medicine
and Oncology
School of Medicine
University of California
San Diego, California 92101

Executive Secretary:

Maxwell, Cyrus, M.D.
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

Members:

****Schein, Philip S., M.D. (1977)**
Head, Division of Medical Oncology
Department of Medicine
Georgetown University Hospital
Washington, D.C. 20007

****Sullivan, Margaret P., M.D. (1977)**
Professor of Pediatrics
The University of Texas
M.D. Anderson Hospital & Tumor Inst.
Houston, Texas 77025

Balcerzak, Stanley P., Jr., M.D. (1979)
Professor of Medicine & Director of
the Division of Hematology & Oncology
The Ohio State University
Columbus, Ohio 43210

Moertel, Charles G., M.D. (1978)
Director of Clinical Cancer Research
Department of Oncology
Mayo Clinic
Rochester, Minnesota 55901

Whitaker, John M.D. (1980)
Capitol Medical Clinic
Austin, Texas

McHugh, Richard, M.D. (1980)
Professor of Biometry
School of Public Health
University of Minnesota
Minneapolis, Minnesota

****Terms expire in June, 1977**

THE UNIVERSITY OF TEXAS SYSTEM CANCER CENTER
M. D. ANDERSON HOSPITAL AND TUMOR INSTITUTE

Interoffice Memorandum

TO: Dr. Clark

DATE: January 14, 1977

FROM: Mel Gallagher

SUBJECT: Oncologic Drugs Advisory Committee

Chairman:

Shimkin, Michael B. M.D. (1978)
Professor of Community Medicine
and Oncology
School of Medicine
University of California
San Diego, California 92101

Executive Secretary:

Maxwell, Cyrus, M.D.
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

Members:

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Department of Medicine
Georgetown University Hospital
Washington, D.C. 20007

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The University of Texas
M.D. Anderson Hospital and Tumor Institute
Houston, Texas 77025

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The Ohio State University
Columbus, Ohio 43210

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Department of Oncology
Mayo Clinic
Rochester, Minnesota 55901

Whitaker, John, M.D. (1980)
Capitol Medical Clinic
Austin, Texas

McHugh, Richard, M.D. (1980)
Professor of Biometry
School of Public Health
University of Minnesota
Minneapolis, Minnesota

- Established on October 24, 1973; expiration date October 24, 1977, but will be routinely renewed by Secretary of HEW this summer.
- Consists of nine members (including the Chairman) appointed by Commissioner of FDA for 4 year terms. (Currently only eight members)
- Met twice during 1976.
- Stated function - "Reviews and evaluates all available data concerning the safety and effectiveness of presently marketed and new prescription drug products proposed for marketing for the treatment of cancer and advises the Commissioner of FDA regarding the current advances, changing concepts, and trends in the field of oncology."
- **Terms expire in June, 1977
- Recommendations from interested parties can be sent to the Executive Secretary, Dr. Maxwell.

cc: Dr. Emil Freireich

CER CENTER
INSTITUTE

January 14, 1977

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THE UNIVERSITY OF TEXAS SYSTEM
CANCER CENTER

MEMORANDUM

DATE: Jan. 14

TO: Dr. Clark

FROM: Mel Gallagher
OFFICE OF THE PRESIDENT

MESSAGE:

Would you want to recommend
two persons to fill the seats which
will be vacated by Dr. Schein and
Dr. Sullivan?

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TO: Dr. Clark

FROM: Mel Gallagher

RE: Draft letter to Dr. Shingleton on the Oncologic Drugs Advisory Committee

Dr. Wm. Shingleton

*OK
RVR* *Not for final*

Attached is a list of the current members of the Oncologic Drugs Advisory Committee. As you will note, the terms of both Dr. Schein and Dr. Sullivan expire in June of this year. Since the AACI adopted a resolution at our January meeting urging that this Advisory Committee of the Food and Drug Administration be given additional authority over the development of investigative new drugs and devices, I thought that the Association might want to recommend physicians to fill the seats being vacated by Dr. Schein and Dr. Sullivan.

Recommendations are now being accepted by Dr. Cyrus Maxwell, Executive Secretary of the Oncologic Drugs Advisory Committee, Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland. Please let me know if I can be of any assistance.

Sincerely,

R. Lee Clark, M.D.

AMERICAN CANCER SOCIETY, INC.

777 THIRD AVENUE • NEW YORK, N.Y. 10017 • (212) 371-2900

February 18, 1977

102
R. LEE CLARK, M. D.
President

Ms. Anita Johnson, Attorney
Health Research Group
2000 P Street, N.W.
Washington, D. C. 20036

Dear Ms. Johnson:

Your letter addressed to me at the American Cancer Society office in New York reached me yesterday.

The discussion of the American Cancer Society representatives about the problem with the Food and Drug Administration and the issuance of Investigational New Drugs (INDs) was expressed last October at a press conference. Since then, articles have been written concerning that interview after rather extensive exploratory investigation by some of the science writers. I am sure you are familiar with the Associated Press report of January 19, 1977, which appeared in numerous papers around the country including the Washington Post on January 20.

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Meanwhile, I met with the senior medical member of the FDA under whom the drug testing activity is conducted. Following this meeting in Washington, D.C., I invited him to attend a meeting of the Association of American Cancer Institutes held at The University of Texas M. D. Anderson Hospital and Tumor Institute. This group of cancer institutes, organized in 1961 by five of us who were directors of what are now called comprehensive cancer centers, is presently composed of fifty-six members. We share many mutual problems in our efforts to expedite the care of the cancer patient. We exchange progress in cancer research in general, as well as various methods to solve managerial problems in running our cancer centers' programs. We are doing all that we can to decrease the extremely long time it takes to generate an idea and take it to the various fields of research for verification until it can be applied at the bedside. We think it is indefensible that we are, generally, unable to carry out such plans in less than fifteen years. We were very hopeful that with the National Cancer Plan this could be done in considerably less time, but this has not been the case to date. Therefore, those of us concerned find it a very sorrowful fact that the more we get involved with governmental bureaucracy, the longer it takes to accomplish anything.

**RESEARCH
EDUCATION
SERVICE**

Ms. Anita Johnson
February 18, 1977
Page two

At the meeting in Houston we had a conference between the leaders of the cancer institutes and the senior physician from the Food and Drug Administration, and including his suggestions the Association of American Cancer Institutes formulated and passed a resolution which is enclosed. We hope this resolution can be carried out. At the same time, we have also asked the National Cancer Institute to continue negotiations with the FDA so that a solution may be found which we can all live with in good conscience.

Also, I am sending you a position statement of the American Cancer Society on the use of new drugs and new drug combinations in the treatment of cancer. This statement was formulated after discussion among members of the American Cancer Society's Medical and Scientific Committee; Dr. Frank Rauscher, ACS Senior Vice President for Research; Dr. Arthur Holleb, ACS Senior Vice President for Medical Affairs; and me.

Answers to the other questions raised in your letter concerning the particulars of the INDs which were delayed over a year or removed from investigation by the FDA order have been provided to you, I see from your letter of February 1, 1977 to Congressman Paul Rogers.

Sincerely yours,



R. Lee Clark, M.D.
President

cc: Dr. Arthur I. Holleb
Dr. Frank J. Rauscher

22

AACI RESOLUTION

RESOLVED

The Association of American Cancer Institutes is concerned about the lag in new anticancer drug development and clinical usage and urges the Federal Drug Administration and the National Cancer Institute to resolve this lag problem as soon as possible. AACI is also concerned about the process of formulation of policy for new anticancer drug investigation and study of new devices.

In order to facilitate resolution of current problems and promote appropriate policy development for anticancer drug study, it is recommended that the Oncologic Drugs Advisory Committee of the FDA be given review responsibilities for Investigational New Drugs (INDs) and related policy matters.

It is requested that the Task 10 Committee of the AACI be charged with carrying these recommendations to the FDA and continue to serve to bring to the attention of the FDA matters of concern to the AACI relative to new anticancer drug development and clinical usage and the study of new devices.

POSITION STATEMENT OF THE AMERICAN CANCER SOCIETY
ON THE USE OF NEW DRUGS AND NEW DRUG
COMBINATIONS IN THE TREATMENT OF CANCER

The American Cancer Society believes that the Food and Drug Administration has, for the most part, served the public well through its regulations that demand drug efficacy including minimal or known and acceptable levels of toxicity. We believe that strict guidelines in the use of drugs must be enforced particularly for those diseases that are subacute, usually non-lethal and certainly for patients that are nonterminal for whom other effective and nontoxic remedies are available.

However the overly strict interpretations of FDA regulations by their staff have greatly impeded the development of potentially useful drugs for cancer patients, especially for those that are or will be terminal because they are refractory to other forms of treatment. Until more exploitable differences are found between normal and cancer cells it must be expected that some toxicity will occur from drugs expressly designed to kill cells. We must rely on the very considerable skills of qualified clinical investigators to use the principles of selective toxicity for the benefit of patients who, having no other recourse, will die from progressive growth of their cancers. NCI and FDA staff have had many negotiations in the past year on this problem and these negotiations still continue. Some progress has been made. Within the past month, the FDA has released all IND applications held up in 1976.

FDA has recently suggested regulating combinations of approved single anti-cancer drugs by requiring a new IND with each combination. This subject has been mentioned in their Oncologic Drug Advisory Group meetings and rejected by the committee. NCI does not believe that new IND's for the use of anti-cancer drugs in combination is required by law. The American Cancer Society supports this position and further, we believe that the cancer patient, particularly the terminal patient, is best served by the prompt application of new drugs or new combinations by qualified investigators, with informed consent of the patient and for which there are indicative laboratory data.

The American Cancer Society is not a regulatory agency. The Society and the National Cancer Institute prefer to have the FDA continue this regulatory activity. A transfer of this important and complex function to the NCI would have to be considered and supported by the American Cancer Society in the unlikely event that agreements cannot be reached to prevent delays in the use of new drugs or new drug combinations for potential benefit to the apparent terminal cancer patient.

Public Citizen

Date Referred

Feb 16

Action: Handle

Prepare reply for my signature

Advise

February 8, 1977

See me

Information

Other

RECEIVED

Dr. R. Lee Clark
American Cancer Society
219 E. 42nd St.
New York, N.Y. 10017

FEB 10

86
OFFICE OF THE
EXECUTIVE
VICE PRESIDENT

Dear Dr. Clark:

A December 3, 1976 letter from the American Cancer Society national representative in Washington, Nathaniel Polster, requested a new amendment to the National Cancer Act to exempt the National Cancer Institute from scrutiny under the Federal Food, Drug and Cosmetic Act. As you know, under the latter Act, the Food and Drug Administration has the obligation to oversee drug experimentation for the purpose of protecting human subjects and designing scientifically-adequate protocols.

Mr. Polster refused to discuss the ACS letter and in fact hung up on me, stating that he had no reason to talk with me since he had "never received any co-operation from [my] office."*

Is it the position of the ACS that legislation is desirable exempting NCI-sponsored drug experiments from FDA scrutiny? Is it your position that legislation is necessary? What circumstances led to Mr. Polster's letter? What problems has ACS had that led to this recommendation? Who in ACS is familiar with the details of the specific drug experiments involved? What steps does ACS intend to take to further progress of the recommended statute?

According to the ACS letter, "The National Cancer Advisory Board, and a large number of biomedical science administrators" support the need for the change. I have been unable to locate any such recommendation, and hope that you can direct me to it. Who are the large number of biomedical science administrators?

If ACS does not support a new statute, what is the problem and solution seen by ACS?

Thank you very much for your time. If you prefer that I telephone you, please inform me of an appropriate time. I am

*The meaning of this is not clear; perhaps you can shed some light on it.

anxious to know the details on the drugs involved.

Yours truly,

Anita Johnson
Anita Johnson, atty.

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February 16, 1977

John S. Spratt, M. D.
Deputy Director, Cancer Center
University of Louisville
Health Sciences Center
Louisville, Kentucky 40201

Dear Jack:

It was nice to see and visit with you in Houston during the AACI meeting in January. Your position at Louisville sounds most interesting. I was happy to learn of your receiving the American Cancer Society Professorship in Clinical Oncology and your election to the graduate faculty there at the cancer center. It seems you are quite satisfied and the move was a most profitable one.

I wish you every success in your private practice and your future association with the University of Louisville.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC:jh



UNIVERSITY OF LOUISVILLE
HEALTH SCIENCES CENTER
LOUISVILLE, KENTUCKY 40201

CANCER CENTER

WALNUT AND
PRESTON STREETS

January 13, 1977

R. Lee Clark, M.D.
President
University of Texas System Cancer Center
Houston, Texas 77025

Dear Lee,

I enjoyed visiting with you in Houston and filling you in on Louisville. As you know I looked around at several places before I decided to separate from Columbia. Some of the schools were a little too far advanced and too rigid in their structure to accomodate a desirable clinical program in cancer. However, I found the environment here at the University of Louisville most receptive to the development of a strong cancer program.

Specifically the Cancer Center is authorized all the way through the Board of Trustees as a graduate institute within the University. It has it's own Director who reports to a three man Board which consists of the Dean of the School of Medicine, the Dean of the Dental School and the Dean of the Graduate School. This Board is primarily for policy support since a great deal of authority is vested directly in the hands of the Director. He has a steering committee to advise him which consists of broad faculty representation and a system of associates in Oncology which brings into the Cancer Center scattered elements of the faculty who wish to concentrate on cancer. There are a number of interesting programs here which are quite productive and a number of others are on the drawing board which will see a continued growth of the program. Louisville is kind of like New Jersey in that there's an awful lot of chemical industry here and one of the more active programs is the one on environmental carcinogenesis concentrating on the vinyl chloride problem.

From my own standpoint I'm particularly attracted by the graduate institute status of the Cancer Center since I have always had an active interest in graduate education and tend to use this vehicle to build up a number of programs. I've already been elected to the graduate faculty and have been site visited for an American Cancer Society Professorship in Clinical Oncology. I also have a private practice outlet which I never had in Columbia and am enjoying the direct patient care side of the Louisville environment.

R. Lee Clark, M.D.
January 13, 1977
Page Two

The situation in Columbia I fear is in for a sustained period of deterioration both at the Medical School under White and at the Cancer Hospital under the present head of the Division of Health. However, the whole situation might end up being salvaged because a Legislative Committee has taken a very active interest in reviewing the cancer program. Through this Committee I have the ear of major legislative committee leadership and hopefully they may make some long-term improvements that will be highly beneficial. I have specifically provided them with legislation from the State of New York and a long consultative report from Robert Goehle on the accommodations of the State Civil Service System in New York for cancer clinicians and cancer scientists at a competitive salary scale. A chance of an umbrella corporation such as Yarbro has tried to sell them existing or surviving in Missouri is still nil. I also happen to believe that these umbrella corporations are detrimental to state supported programs. You may have a different opinion but I can provide you with quite a number of case studies which documents the damage that these corporations did do.

I'll be glad to visit with you further anytime on the situation. With best wishes.

Sincerely,



John S. Spratt, Jr., M.D.
Deputy Director, Cancer Center

JSS: bak

February 8, 1977

John S. Spratt, M.D.
Co-Director
Cancer Center
University of Louisville
Louisville, Kentucky 40202

Dear Jack:

It was nice seeing you in New York but I did not have the opportunity to congratulate you on your new appointment at the University of Louisville and also upon your receiving the American Cancer Society Career Professorship Award. We at M.D. Anderson Hospital and Tumor Institute extend to you congratulations and wish for you all success in this new important tour of duty and with the accolade of a career professorship of surgery upon your shoulders.

Very sincerely,

Murray M. Copeland, M.D.
Vice President
University Cancer Foundation

MMC:ds

cc: R. Lee Clark, M.D. ✓

M. D. ANDERSON HOSPITAL
RECEIVED
OFFICE OF THE PRESIDENT

THE UNIVERSITY OF TEXAS

Dr. Spratt accepts Louisville U. position

*more
about
2*

The resignation of Dr. John S. Spratt, Jr., director of the Department of Surgery at Ellis Fischel State Cancer Hospital, was announced December 8 by Dr. Herbert R. Domke, director of the Missouri Division of Health. Dr. Spratt's resignation was effective December 6 and ends a 16-year association with the hospital. Dr. Spratt was director of the Cancer Research Center from 1965 to August 1976.

Dr. Spratt has accepted positions as professor of surgery (oncology) at the University of Louisville Health Science Center, and co-director, Cancer Center, University of Louisville.

Commenting on Dr. Spratt's resignation, Virgil T. Yates, EFSCH administrator, said, "Dr. Spratt leaves behind many friends in the hospital and Columbia. Dr. Spratt has contributed a great deal to Ellis Fischel Hospital, the Cancer Research Center, and to the cancer programs of Missouri. He will be missed."

Dr. Spratt received his M.D. degree from the University of Texas Southwestern Medical School in Dallas in 1952. He served his internship in surgery at Barnes Hospital, St. Louis, in 1952-53, and was assistant resident in surgery there from 1955 until 1957. Dr. Spratt has been professor of surgery (since 1966) at the University of Missouri-Columbia School of Medicine.

A prolific writer, Dr. Spratt is the author of more than 130 medical journal articles and is author or co-author

of 7 medical books.

Dr. Spratt has held several academic appointments at Washington University School of Medicine, St. Louis, in addition to the University of Missouri-Columbia School of Medicine. His professional appointments since 1959 include Barnes and Allied Hospitals, St. Louis; Cochran Veterans Administration Hospital, St. Louis; St. Louis City Hospitals; Ellis Fischel State Cancer Hospital, Columbia; the Cancer Research Center, Columbia; Bothwell Memorial Hospital, Sedalia; Boone County Hospital, Columbia; Harry S. Truman Veterans Administration Hospital, Columbia; consultant in surgery at Jewish Hospital, St. Louis; and consultant in cancer communication, Franklin Institute, Philadelphia.

Dr. Spratt was on active duty as a naval officer from 1953 to 1955. He holds the rank of captain in the U.S. Naval Reserve. He is now executive officer, U.S. Naval Regional Medical Center 2912, St. Louis.

Since 1962, Dr. Spratt has been appointed to and served on many special medical boards and as a member of professional and health care associations. He also is on the editorial boards of five medical journals. Professional listings include Who's Who in the Midwest, American Men of Science, Directory of Medical Specialists and World Who's Who in Science. He has been active for many years in civic and service organizations in the Columbia area.

MIRROR 7, Nov Dec, 1976 ⁵ Columns Mo.

ROSWELL PARK MEMORIAL INSTITUTE



Department of Health • State of New York
Hollis S. Ingraham, M.D., Commissioner

666 Elm Street • Buffalo, New York 14203
Gerald P. Murphy, M.D., Director

February 15, 1977

Dr. R. Lee Clark, President
University of Texas System Cancer Center
M. D. Anderson Hospital and Tumor Institute
Texas Medical Center
Houston, Texas 77030

Dear Dr. Clark:

I wish to acknowledge receipt of your check in the amount of \$500.00 as payment of Annual Dues for 1977 for membership in the Association of American Cancer Institutes.

I appreciate your prompt attention to this matter.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "E. A. Mirand".

E. A. Mirand
Associate Institute Director
and Professor, R.P.M.I.;
Secretary-Treasurer, A.A.C.I.

EAM:co

10.2
February 10, 1977

Doctor Edwin A. Mirand, Secretary-Treasurer
Association of American Cancer Institute
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14263

Dear Doctor Mirand:

Doctor Clark asked that we send you the minutes of a meeting held at Memorial Sloan-Kettering, December 7, on the Cancer Patient Data Sharing project. This meeting included representatives of the five (5) AACI member institutions participating in the data sharing project with-CICA. Another meeting on the Cancer Patient Data System was held Monday, January 10, in Houston, and a copy of the minutes of that meeting are attached.

Also, we are sending you a copy of the report on the regional meeting to discuss planning of Centralized Patient Data Exchange System internationally which was held at Villejuif, on December 17.

I hope this information will be useful to you.

Sincerely yours,

(Mrs.) JoAnne Hale
Administrative Assistant to
R. Lee Clark, M. D

JAH/m
encls

JoAnne
cc:
Complete
all
encls.

10.2
February 8, 1977

Dr. Wm. W. Shingleton, President
Association of American Cancer Institutes
Duke Comprehensive Cancer Center
Durham, North Carolina

Dear Bill:

Thank you for your invitation to serve as AACI liaison member to the CICA committee and to serve on the AACI nominating committee for 1977. I shall be pleased to serve in these areas and have forwarded the necessary papers to Dr. E. A. Mirand.

I was happy to learn that you have been appointed to the National Cancer Advisory Board. You will be of great assistance to this Board.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC/m



association of american cancer institutes

OFFICERS

PRESIDENT ALBERT H. OWENS, JR., M.D.
John Hopkins University Oncology Center, Baltimore, Maryland

VICE PRESIDENT WILLIAM W. SHINGLETON, M.D.
Duke Comprehensive Cancer Center, Durham, North Carolina

SECRETARY-TREASURER E.A. MIRAND, Ph.D.
Roswell Park Memorial Institute, Buffalo, New York

January 19, 1977

Dr. R. Lee Clark, President
University of Texas System Cancer Center
M. D. Anderson Hospital and Tumor Institute
Texas Medical Center
Houston, Texas 77030

Dear Dr. Clark:

I should like to have you serve as the Liaison Representative to the UICC/CICA for the AACI for the year 1977.

Please complete the attached form and return it to the Secretary-Treasurer at your earliest convenient.

I hope you will be able to serve in this capacity and look forward to working with you in the coming year.

Sincerely yours,

Wm W. Shingleton

Wm. W. Shingleton, M. D.
President

WWS/o
Attachment

BOARD OF DIRECTORS

R. Lee Clark, M.D., Chairman
Houston, Texas

Edward J. Beattie, Jr., M.D.
New York, New York

Murray M. Copeland, M.D.
Houston Texas

Lewis L. Coriell, M.D.
Canden, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

Please check one:

I do X , I do not _____ accept the appointment to serve as Liaison
Representative to the UICC/CICA for the A.A.C.I. for the year 1977.

R. Lee Clark
Signature

Date January 25, 1977

Return to:

Dr. E. A. Mirand, Secretary-Treasurer, AACI
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14263



association of american cancer institutes

OFFICERS

PRESIDENT ALBERT H. OWENS, JR., M.D.
John Hopkins University Oncology Center, Baltimore, Maryland

VICE PRESIDENT WILLIAM W. SHINGLETON, M.D.
Duke Comprehensive Cancer Center, Durham, North Carolina

SECRETARY-TREASURER E.A. MIRAND, Ph.D.
Roswell Park Memorial Institute, Buffalo, New York

January 19, 1977

Dr. R. Lee Clark, President
University of Texas System Cancer Center
M. D. Anderson Hospital and Tumor Institute
Texas Medical Center
Houston, Texas 77030

Dear Dr. Clark:

I should like to have you serve in your capacity as a
Past President of the AACI, as a member of the Nominating Committee
for the year 1977.

Please complete the attached form and return it to the
Secretary-Treasurer at your earliest convenience.

I trust you will be able to accept this appointment and
I look forward to the opportunity of working with you in the
coming year.

Sincerely yours,

Wm W Shingleton
Wm. W. Shingleton, M. D.
President

WWS/o
Attachment

BOARD OF DIRECTORS

R. Lee Clark, M.D., Chairman
Houston, Texas

Edward J. Beattie, Jr., M.D.
New York, New York

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Houston Texas

Lewis L. Coriell, M.D.
Candem, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

Please check one:

I do X, I do not _____ accept the appointment to serve as a member
of the Nominating Committee for the A.A.C.I. for the year 1977.

R. Lee Clark

Signature

Date January 25, 1977

Return to:

Dr. E. A. Mirand, Secretary-Treasurer, AACI
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14263

10.2
January 28, 1977

Dr. Jan Steiner
Director Designate
Illinois Cancer Council
37 South Wabash Avenue
Chicago, Illinois 60603

Dear Doctor Steiner:

It was indeed a pleasure to see you at the meeting of the Association of American Cancer Institutes in Houston. I am delighted that you have joined the team in Chicago. You have assumed a very difficult job, however, if anyone can make the program go, I am sure you can. I have always enjoyed your sagacious comments and views on the various site visits on which we have the opportunity to collaborate.

We extend to you an open invitation to visit our institution, and if you will advise us in advance, we will arrange an agenda for your review of the various activities here in which you might be interested. Also, when you come to Houston, we would like for you to give a presentation to our staff. If you can, we would be happy to reimburse you for your expenses.

Sincerely yours,

R. Lee Clark, M.D.
President

RLC:jb

bc: Dr. G. B. Blumenschein
Dr. R. C. Hickey



ILLINOIS CANCER COUNCIL

37 South Wabash Avenue • Chicago, Illinois 60603 • 312-346-9813

January 11, 1977

R. Lee Clark, M.D.
President
The University of Texas System
Cancer Center
M.D. Anderson Hospital and
Tumor Institute
6723 Bertner Avenue
Houston, Texas 77030

Dear Lee:

This is just a brief note to tell you how much I enjoyed the meeting of the AACI in Houston. Unfortunately I had to rush back because of some pressing business in Chicago and consequently I missed the opportunity to visit with you as you suggested. I will, however, take a raincheck on this invitation, since there are many things which I would like to learn from you.

Again, many thanks for your hospitality.

Sincerely yours,

Jan W. Steiner, M.D.
Director Designate

JWS:sa

10.2

Mr. E. R. Gilley

January 25, 1977

Office of the President

1977 Annual Dues - Association of American Cancer Institutes

This memo is a request for you to remit the 1977 annual dues, in the amount of \$500.00, to the Association of American Cancer Institutes for our institution.

As requested on the enclosed statement, please make the check payable to the Association of American Cancer Institutes and send it to the following address:

Dr. E. A. Mirand
Secretary-Treasurer
Association of American Cancer Institutes
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14203

You may wish to use the same source of funds as used in previous years.

R. Lee Clark, M. D.
President

RLC:jh
Enclosure



association of american cancer institutes

OFFICERS

File to handle
PRESIDENT ALBERT H. OWENS, JR., M.D.
John Hopkins University Oncology Center, Baltimore, Maryland

VICE PRESIDENT WILLIAM W. SHINGLETON, M.D.
Duke Comprehensive Cancer Center, Durham, North Carolina

SECRETARY-TREASURER E.A. MIRAND, Ph.D.
Roswell Park Memorial Institute, Buffalo, New York

January 19, 1977

MEMO TO: Dr. R. Lee Clark, University of Texas System Cancer Center
FROM: Dr. E. A. Mirand, Secretary-Treasurer *EAM*
SUBJECT: Annual Dues for 1977

Annual dues are established by the Board of Directors of the Association of American Cancer Institutes in such amounts as it deems necessary to defray operating expenses. It has been recommended by the Board of Directors that these dues should be \$500.00 for each regular member organization in the AACI. Please find enclosed a statement for the annual dues for the year 1977.

Please make your check payable to the Association of American Cancer Institutes, attention of Dr. E. A. Mirand, Secretary-Treasurer. It would be appreciated if payment of the annual dues could be made by February 15, 1977.

EAM:co
Enclosure

W. D. ANDERSON HOSPITAL
RECEIVED
OFFICE OF THE PRESIDENT
JAN 24 1977

THE UNIVERSITY OF TEXAS

BOARD OF DIRECTORS

R. Lee Clark, M.D., Chairman
Houston, Texas

Edward J. Beattie, Jr., M.D.
New York, New York

Murray M. Copeland, M.D.
Houston Texas

Lewis L. Coriell, M.D.
Canden, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin

STATEMENT

ASSOCIATION OF AMERICAN CANCER INSTITUTES

Annual Dues for 1977

Regular Membership ----- \$ 500.00

Please make check payable to:

Association of American Cancer Institutes

Send to:

Dr. E. A. Mirand, Secretary-Treasurer, AACI
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14263

NOTE: It would be appreciated if dues could be paid by Feb. 15, 1977.

10.2

January 18, 1977

Dr. Albert Owens
Director
Johns Hopkins University Oncology
Center
332 Carnegie
Baltimore, Maryland 21205

Dear Al:

Thank you for your thoughtful comments regarding the AACI meeting. I believe it was a most successful meeting with a good representation of the members.

Your invitation to participate in the dedication ceremonies of the Johns Hopkins Center is certainly appreciated. I have a scheduled American Cancer Society Executive Committee meeting April 13-15 and as I mentioned a proposed trip to China beginning April 18. This trip has not been confirmed as of this date however I am hesitant to make other commitments at this time.

We have ordered a representative group of pictures from the dedication activities and these should be available in the near future.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC:jh

P.S. The Dedication of your facility has the highest priority - however, China says I must attend - any other time for you and I will make it.

jh

THE JOHNS HOPKINS UNIVERSITY
SCHOOL OF MEDICINE

ONCOLOGY CENTER
301-955-3300

THE JOHNS HOPKINS HOSPITAL
BALTIMORE, MARYLAND 21205

January 13, 1977

Dr. R. Lee Clark
University of Texas System Cancer
Center
M.D. Anderson Hospital and Tumor
Institute
Texas Medical Center
Houston, Texas 77025

Dear Lee:

I am sorry that I didn't get a chance to say good-by before I had to leave for the airport. It was a good meeting and, as usual, you were a most gracious host. Please know how much all of us appreciate the very fine arrangements which you and your staff made.

You will recall that we spoke about your participating in the dedication of our Center at Hopkins on April 17-18. As I understand it, you were concerned that you would be leaving for China then. However, please let me know whether your memory was correct or not. There are many reasons why I would like to have you participate in the dedication, so I hope you will find that your calendar is clear.

I will mention one other item that I am still concerned about. You will recall that I participated in your dedication ceremony a few months ago. At one point you indicated that some one in your office might be kind enough to send me a few photos of the occasion when they were ready. I don't believe anything ever got to me and I would still appreciate receiving a remembrance of the event if it's not too much trouble.

*jh
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to immediately*

Sincerely,

Al

Albert H. Owens, Jr., M.D.
Director

AHO:rar

10.2

January 17, 1977

Dr. Tapas K. Pradhan
Assistant Professor of Oncology
Howard University Cancer Research Center
2041 Georgia Avenue, N. W.
Washington, D. C. 20060

Dear Doctor Pradhan:

We appreciate your letter of January 13, and your interest in the Association of American Cancer Institutes. I am forwarding your letter to Dr. E. A. Mirand, Secretary-Treasurer of the Association, so that he may send you the information you have requested.

Thank you for your interest.

Sincerely yours,

R. Lee Clark, M. D.
President

RLC:jh
cc: Dr. E. A. Mirand

*1/26 - Asked RLC if Cy should go to Dr. White at Columbia -
No response -*



HOWARD UNIVERSITY CANCER RESEARCH CENTER

COLLEGE OF MEDICINE

WASHINGTON, D. C. 20059

OFFICE OF THE ASSOCIATE DIRECTOR
Area Code 202-462-8488



DEPARTMENT OF ONCOLOGY
HOWARD UNIVERSITY HOSPITAL
2041 Georgia Avenue, N.W.
Washington, D. C. 20060
745-1406, 07, 08, 09

January 13, 1977

Dr. R. Lee Clark
President
University of Texas System Cancer Center
M. D. Anderson Hospital and Tumor Institute
Texas Medical Center
Houston, Texas 77030

Dear Dr. Clark:

I would like to receive the following information regarding membership in the Association of American Cancer Institutes (AACI):

1. Eligibility of membership.
2. Annual membership fee.
3. Annual meetings organized by AACI.
4. Other relevant information regarding the AACI.

If possible, please send me an application form and other informative material of the AACI, at your earliest convenience.

Thank you for your kind attention.

Sincerely,

Tapas K. Pradhan, Ph. D.
Assistant Professor of Oncology

TKP:bjo'c



association of american cancer institutes

10.2

OFFICERS

PRESIDENT ALBERT H. OWENS, JR., M.D.
John Hopkins University Oncology Center, Baltimore, Maryland

VICE PRESIDENT WILLIAM W. SHINGLETON, M.D.
Duke Comprehensive Cancer Center, Durham, North Carolina

SECRETARY-TREASURER E.A. MIRAND, Ph.D.
Roswell Park Memorial Institute, Buffalo, New York

January 10, 1977

Dr. Denman Hammond
Los Angeles County
University of Southern
California Comprehensive
Cancer Center
2025 Zonal Avenue
Los Angeles, California 90033

Dear Denny:

The concerns expressed in your letter of January 3 to Ed Mirand distress me. The wording of the minutes is unfortunate and the implications you drew, though understandable are not correct.

My purpose in responding is to assure you that the AACI Board of Directors is very grateful for the liaison service which you performed with the ACCC. No expressions of dissatisfaction entered our deliberations. On the contrary, we were concerned that the good work you started be carried on by a suitably qualified successor who could devote the required time and energy to the work.

I believe that a great many of us are working far too hard at too many tasks. As the AACI grows in membership, more individuals should share in the responsibility of carrying its work forward. It was with these general perceptions in mind that we acknowledged your resignation and asked John Yarbro to serve as your successor in the ACCC liaison work.

I hope this "sets the record straight". I know everyone on the Board would wish to join me in this expression.

Sincerely,

Albert H. Owens, Jr., M.D.
President

AHO:rar

cc: Drs. R.L. Clark and E.A. Mirand
BOARD OF DIRECTORS

R. Lee Clark, M.D., Chairman
Houston, Texas

Edward J. Beattie, Jr., M.D.
New York, New York

Murray M. Copeland, M.D.
Houston, Texas

Lewis L. Coriell, M.D.
Candor, New Jersey

Charles A. Evans, M.D.
Seattle, Washington

G. Denman Hammond, M.D.
Los Angeles, California

Henry C. Pitot, M.D.
Madison, Wisconsin



LOS ANGELES COUNTY — UNIVERSITY OF SOUTHERN CALIFORNIA
COMPREHENSIVE CANCER CENTER

2025 Zonal Avenue • Los Angeles, California 90033 • (213) 226-2008

OFFICE OF THE DIRECTOR
KEITH 509

January 3, 1977

jh

Dr. Edwin A. Mirand
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14203

Dear Ed:

I would like to provide clarification and correction of the minutes of the meeting of the Board of Directors of the Association of American Cancer Institutes which was held in Houston on October 1, 1976. On page seven there is reference to my resignation as the representative of the AACI to the Board of Directors of the Association of Community Cancer Centers.

The minutes imply that the ACCC expressed some dissatisfaction with my lack of interest and that my resignation had been requested by the ACCC since they had been "miffed" by my performance.

The minutes are incorrect in these respects. I feel that the liaison between the AACI and the ACCC is an important one, so I gladly accepted designation as the AACI representative to the Board of Directors of the ACCC. I attended two meetings of the Board of Directors and have reported on the activities of the ACCC at the meetings of the AACI on at least two occasions.

I have been an active supporter of ACCC since its inception. I originally proposed to AACI that a liaison be established. I have provided to ACCC on two occasions detailed letters in support of applications submitted by ACCC to the NCI.

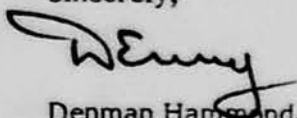
After a year, I felt I could not continue to give membership on the ACCC Board the priority which it deserved, so I advised Dr. James Donovan that I wished to resign, and would request Dr. Owens to appoint another representative. I advised Dr. Owens of this verbally last spring. Since I was not aware that any action had been taken, I put my resignation in writing to Dr. Gayle Ketterhagen, president of the ACCC and to Dr. Owens, in the summer of 1976. I received a very kind letter from Dr. Ketterhagen understanding the reasons for my resignation and generously appreciating the contributions and suggestions I had made to ACCC.

Dr. Edwin A. Mirand
January 3, 1977
Page 2.

I would like the record of this meeting to be corrected since it implies that I lack interest in the ACCC and that the ACCC somehow initiated my resignation from its Board of Directors. I don't believe either of those implications is correct.

Thank you very much.

Sincerely,



Denman Hammond, M.D.
Director,
Associate Dean

DH/acp

cc: Albert Owens, M.D.
President, AACI
Johns Hopkins University

R. Lee Clark, M.D.
President
M.D. Anderson Hospital and Tumor Institute



THE UNIVERSITY OF TEXAS SYSTEM
CANCER CENTER

Texas Medical Center Houston, Texas 77030



OFFICE OF THE PRESIDENT

13 October 1976

Edwin A. Mirand, Ph.D.
Associate Institute Director
Roswell Park Memorial Institute
666 Elm Street
Buffalo, New York 14263

Dear Dr. Mirand:

Enclosed is the draft of the AACI Board of Directors minutes for your approval and distribution. Neither Dr. Clark nor you attended the meeting (Dr. Clark was present for approximately 10 minutes), so we also forwarded a copy of the draft to Dr. Owens, who presided at this meeting and is the best person to check the accuracy of the information included. Perhaps you would like to check with Dr. Owens regarding his opinion of the minutes before they are finalized and distributed.

I regret that you were here so briefly, as it is always so pleasant to visit with you and to hear your views and perspectives of the AACI activities and other matters. I hope you will be here for a longer period of time in January, and I sincerely hope the weather will be better here than in Buffalo. I can almost guarantee that it will not snow here.

Sincerely,

(Ms.) B. J. Kolenda
Research Analyst

Encl.

cc: Dr. A. H. Owens, Jr.



ASSOCIATION OF AMERICAN CANCER INSTITUTESBOARD OF DIRECTORS

October 1, 1976
Houston, Texas

PRESENT: Dr. Albert Owens, President (presided)
Dr. R. Lee Clark, Chairman
Dr. E.J. Beattie
Dr. M. M. Copeland
Dr. Lewis Coriell
Dr. William Shingleton

ABSENT: Dr. Charles Evans
Dr. Denman Hammond
Dr. E. A. Mirand
Dr. Henry Pitot

<u>GUESTS:</u>	Dr. James Bowen	Department of Virology, MDAH
	Dr. P. Denoix	Institut Gustave Roussy, Villejuif, France
	Dr. E. J. Freireich	Dept. of Developmental Therapeutics, MDAH
	Dr. Albert E. Gunn	Head, Rehabilitation Center, MDAH
	Dr. Felix Haas	Office of Research, MDAH
	Dr. Robert Hickey	Director, MDAH

Dr. Clark was delayed in arriving at the meeting, and Dr. Owens presided.

FDA restrictions
on INDs

Dr. Owens invited Dr. E. J. Freireich to give a brief review of the presentation he prepared for the President's Cancer Panel meeting during the afternoon. The essence of the presentation was that the regulatory mechanism of the FDA with regard to Investigational New Drugs (INDs) for cancer patients has become so repressive that clinical research in cancer centers has essentially been halted. The chief problem is the determination of the FDA to interpret the protective laws intended for healthy citizens in exactly the same manner for cancer patients, who are facing potentially fatal diseases for which aggressive therapeutic measures and new drugs are essential. The obstructive nature of the FDA regulatory interpretations

is based, not on clinically informed judgments of the efficacy or toxicity of drugs, but on nonmedical matters such as progress reports, forms to be completed by specified deadlines, numbers of animals on which drugs were tested, etc. and regarding informed consent wording, which the FDA interprets as "coercive" when terms such as "therapy", "treatment", etc. are used.

DA proposals in
Federal Register
e: "experimental
devices & in vitro
diagnostics"

In addition, FDA proposals published in the Federal Register (August 20, 1976) include 11 rules for disqualification of investigators (Appendix I) which are so restrictive and punitive that clinical and much basic research will be brought to a virtual standstill.

recombinant DNA
research

Dr. Felix Haas (Head, Office of Research, MDAH) pointed out that the regulations dealing with recombinant DNA studies are so loosely written and may be so restrictively interpreted and regulated that cancer research in almost every field that includes in vivo and in vitro DNA research might be affected.

suggested Formal
objections

Dr. Albert Gunn of MDAH, who has both an M.D. and L.L.D. degree, was invited to make some remarks regarding these issues. Dr. Gunn had discussed these matters recently with a senior FDA employee. He ascertained that (1) FDA does indeed intend to scrutinize the NCI more closely in the future; (2) FDA does not agree that the desperate status of cancer patients justifies any different interpretive position than the FDA is taking for healthy citizens, (3) the new IND regulations are not substantially different than the previous ones, (4) FDA has always had the power to disqualify investigators who were guilty of infractions of regulations, and that the only differences were in the reasons for disqualification. An example of this is that presently, if the investigator has obtained a proper informed

consent from the patient(s) and begins the research project but has not sought clearance from his/her institutional surveillance committee, the investigator is disqualified permanently and his/her name is published widely within the scientific community.

Dr. Gunn suggested that many individuals within the scientific and clinical should community object strongly to this and similar positions taken by the FDA and claim that there should be strong evidence of willful intent to disregard regulations before such strong action is taken by the FDA or any other regulatory organization. The very nature of research requires freedom of judgment and action, and unless there is evidence of fraudulent intent, such restrictive interpretations of the law should be prohibited.

- Suggested
Objections to:
1. Permanent disqualification of an investigator for infractions without evidence of willful intent; wide publication of disqualification.
 2. Determination of validity of experiment by non-qualified regulatory personnel; permanent denial of further INDs or investigational devices if experiment judged not valid.
 3. Institutional suspension if any member of the institutional research team is under temporary suspension.
 4. Release of patient names to FDA and other regulatory agencies upon demand; violates the traditional patient-physician confidentiality; cannot and should not be done unless patient consents to the release of the information.

Deadline for
Responses to
New Regulations

A certain urgency is required for compliance with the opportunity to respond to the new regulations prior to finalization. A letter, dated September 30, indicated that October 19 would be the deadline for receipt and consideration of responses, although there is some indication that the committee will

begin to finalize the regulations October 4. It is believed, however, that the committee will consider objections that arrive past the October 19 deadline. Mr. Merrill is the General Counsel and Miss Hunter, in Mr. Merrill's office, is the individual within FDA who is responsible for receiving the responses. Other suggestions were:

1. Strong objections to the attitude of FDA that an investigator (and his institution) is guilty until he is proven to be innocent.
2. Before these regulations are finalized and adopted, others should be drafted spelling out disciplinary action to be taken against FDA regulators who are guilty of making "frivolous decisions which are detrimental to the conduct of a valid research project".
3. Dr. Gunn suggested that, when the opportunity presents itself, accused investigators or institutions attend discussions of infractions accompanied by legal counsel with the right of cross examination.

AACI Position

It was agreed by the Board of Directors of the AACI that the organization must go on record in opposition to the restrictive attitude and regulations of the FDA with regard to clinical cancer investigative work.

ACTION

voted by the Board

Dr. Owens intends to write to Gordon Zubrod and Emil Frei requesting a statement regarding the position to be taken by clinical investigators which can be endorsed and submitted as a resolution by AACI to the President of the U.S.

ACTION

Dr. Owens intends to draft a cover letter to accompany the letter drafted by Drs. R. Lee Clark and Robert C. Hickey to Mr. Schmidt of the Federal Drug Administration indicating that the Board of Directors of the AACI considers the medical needs of cancer patients to be dramatically different from those of the average healthy citizen and believes that special considerations need to be made with regard to regulatory procedure in monitoring the use

of investigational new cancer drugs (Appendix II). If time permits, this letter will be circulated among the AACI members for endorsement.

Governmental
Representatives

Dr. Copeland suggested, and the Board endorsed, the need to contact personally all governmental representatives and enlist their support in maintaining the freedom so necessary to conduct effective research, and particularly cancer research.

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National Tumor
Registrars' Assn.

Dr. Copeland referred to a letter (Appendix III) addressed to Dr. Owens regarding the National Tumor Registrars' Association (NIRA) which was recently organized (May 14, 1974). These registrars represent 295 hospitals of approximately 750 hospitals whose cancer services and tumor registries are approved by the American College of Surgeons. The purposes of the organization are to promote education regarding the value of tumor registries and to encourage a higher quality performance in the maintenance of tumor registries, to be of benefit to cancer patients and to physicians. In the future, members of this organization intend to assist other hospitals to organize registries and to encourage nonmember registries to join the organization. Dr. Mayer of the American College of Surgeons, Dr. Gerald Murphy of Roswell Park Memorial Institute, and Dr. Copeland are advisors to this group. Dr. Copeland recommended to the group that, rather than attempt to establish an independent national headquarters, they affiliate with a senior medical organization such as the AACI, a suggestion to which they were very receptive. Dr. Copeland believes that if this organization would headquarter in one of the member AACI institutions everyone would benefit more than if it tried to function independently. Mrs. Vida Peterson of Pittsburg is the President of the NIRA, and she and other officers seem

very enthusiastic about assistance from an organization such as AACI in obtaining contracts and grants in the future.

The Board members agreed that discussion of affiliation with the NIRA should be included on the agenda of the January 1977 meeting of the AACI. Dr. Owens asked Dr. Copeland to obtain more information about the organization and submit it to him and Dr. Mirand for wide circulation among AACI members before the January meeting, which Dr. Copeland agreed to do.

ACTION

Proposed Independent Cancer Control Organization

It has come to the attention of several AACI members that at a meeting in Chicago of comprehensive cancer center representatives of the cancer control outreach programs, discussion occurred regarding the possibility of creating an independent organization for cancer control activities. It was agreed that what would be attempted by such an organization would probably

ACTION

overlap and possibly conflict with the AACI Task 12. Dr. Beattie agreed that he would discuss the exact objectives of the organization with Dr. Guy Robbins, who chaired the Chicago meeting, and report back to the Board members.

AACI 12-Task Contract

The AACI contract to carry out the 12 tasks is still awaiting negotiation, and Dr. Owens has an appointment with Dr. Guy Newell on Tuesday, October 5 to discuss the status of the contract.

ISAs

On August 10 several members of the AACI were attending a meeting in Washington, and a very well-informed attorney, Ms. Lillie Engstrom, who is affiliated with CDP Associates, gave an excellent summary statement of the Health Services Agencies and a suggested plan of action. It was suggested and approved by the Board that Ms. Engstrom be invited to give the same presentation to the AACI members at the January meeting.

ACTION

ACCC

The Association of Community Cancer Centers had its grant application disapproved by the NCI, and no member of the Board knows the exact status

of the organization at this time. Dr. Denman Hammond was appointed by AACI to be liaison member to the AACC meetings, but he has not attended any meetings since he was appointed. The AACC is slightly miffed about the apparent lack of interest, and Dr. Hammond has resigned from the appointment. The Board approved the appointment of Dr. John Yarbrow as the AACI liaison member to the AACC, since he is already on the AACC Board of Directors. The AACC is preparing suggestions for changes in the National Cancer Act and the AACI needs to be informed about what their proposals are.

ACTION

National Ca. Act
Proposed Changes

There was brief discussion about the 9 proposed changes of the National Cancer Act. It was agreed that the AACI would endorse the suggested change that would give the Director of NCI authority "to collect data which exists in various tumor registries and cancer research data banks throughout the country" only if the information sought is tumor registry information and not cancer patient data such as that which the AACI members intend to exchange with each other under Tasks 3,4,5 of the AACI Plan.

It was suggested that Dr. Clark be asked to give a presentation to the Board regarding the National Cancer Act changes, about whom to contact and specifically about what. (Dr. Clark was unable to attend the Board meeting for more than a few minutes because of a conflicting meeting for which he was expected to be host.)

NCI Intrainstitu-
tional Committee
to Consider Centers

Dr. Clark (past AACI president), Dr. Owens (current president) and Dr. Shingleton (president-elect) were previously appointed as a liaison committee of the AACI to meet at regular intervals with the Director of NCI and NCI staff members to discuss the role of cancer centers of the country in the National Cancer Plan. All agreed to meet at least 4 times per year to discuss (1) cancer center funding, (2) responsibilities and

resources of the NCI as related to the comprehensive cancer centers and (3) the defined priorities in the centers' role in the national program. The Board members agreed that, since Dr. Rauscher is to leave his position as Director of NCI on November 1, 1976 and since the NCI budget has now been approved by the Congress over the President's veto, it is urgent for center directors to discuss the budget allocations of the NCI very soon with Dr. Rauscher. Dr. Owens expressed his intention to discuss such a meeting with Dr. Rauscher while he is attending the dedication of the Anderson buildings in Houston, and would suggest that Mr. Cal Baldwin, Budget Officer, attend the meeting with Dr. Rauscher. The Board members agreed that there is a great need to upgrade the image of the cancer centers, and that probably the best mechanism will be the patient data system which will demonstrate that the centers are doing a better job of increasing survival of cancer patients and extending useful life even when cure is not achieved.

ACTION

Candidates for
Director-NCI

Board members reviewed the names of the 12 suggested candidates for the position of Director of NCI to replace Dr. Rauscher. It was agreed that the AACI should take no official position regarding the candidates but should endorse candidates individually.

CICA Interest in
Cancer Patient Data
System

Dr. Hickey informed the AACI Board members that the UIOC Committee for International Collaborative Activities (CICA) is very interested in participating in the AACI Task 3,4,5. Dr. Hickey indicated that all problems regarding nomenclature and staging have been solved and the system is ready to be implemented, but that the NCI is still "foot-dragging" about the contract to be awarded for the system. Dr. Rauscher announced recently that he wishes for each NCI division head to cut his/her budget by 3%, and Dr. O'Connor agreed to cut the OCPDS from his budget and to put the project

out for competitive contract negotiation. The Board members agreed that probably the best thing to do is to forget about the proposed AACI contract for this task activity and to initiate the system immediately among themselves. Dr. Hickey said the grant proposal is almost completed by the Anderson Hospital to compete for this system and they plan to go ahead with it. Anderson has been ready since January 1976, and if any of the other AACI institutions wish to be involved in the system and provide their data, the system can begin immediately. Dr. Beattie and Dr. Shingleton said their institutions are ready to begin, and the other Board members expressed their willingness to participate. The consensus was that it probably is not necessary to try to get 11 or 12 of the AACI members together before beginning, and that since the CICA is interested, we should go ahead with the original plan to do this independently of NCI. The CICA members seem to wish the AACI to lead in this enterprise. It was suggested that, if the NCI grant or contract funding does not materialize, a charge per patient entry in the system could be made to each institution for use in support of the system. MDAH can serve as the headquarters in the USA and Institut Jules Bordet in Brussels for Europe. MDAH will go ahead with the grant application since so much work has already been done on it. This plan will be submitted to the full membership at the January meeting of the AACI.

ACTION

ACTION

Carcinogenesis
Workshop

Dr. Shingleton gave a progress report on the arrangements for the Carcinogenesis Workshop to take place immediately following the AACI meeting in January in Houston. There was some confusion about when the Carcinogenesis meeting is to begin - Dr. Shingleton said the afternoon of the 11th, but the agenda has the AACI meeting scheduled for two full days, the 10th and the 11th and the carcinogenesis meeting for the 12th and 13th. All concerned

were to check out the original correspondence to clarify this matter.

It was suggested that another Board of Directors should take place at that time, but no final time was chosen for the meeting.

The meeting was adjourned at 12:10 p.m. for lunch.

Minutes prepared by Ms. B. J. Kolenda
Research Analyst
M. D. Anderson Hospital

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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924 WESTWOOD BOULEVARD SUITE 650
LOS ANGELES, CALIFORNIA 90024

January 5, 1977

yh
match

file
1/12

R. Lee Clark, M.D.
President
M.D. Anderson Hospital
6723 Bertner Avenue
Houston, Texas 77025

Dear Dr. Clark:

Thank you for your thoughtful telegram and the kind sentiments therein. We will very much look forward to working in the capacity of a Comprehensive Cancer Center with you, the A.A.C.I., and with our counterpart Comprehensive Centers in the National Program toward our commonly-held objectives.

Very best wishes for the New Year!

Sincerely,

Rich Steckel

Richard J. Steckel, M.D.
Director, UCLA Comprehensive Cancer Center

RJS:rn



Tele ax

CALL
LETTERS **CDA 158810**

CHARGE
TO **Office of the President**

**DR. RICHARD J. STECKEL
DIRECTOR
UCLA CANCER CENTER
UCLA MEDICAL CENTER
924 WESTWOOD BLVD.
LOS ANGELES, CALIFORNIA 90024**

**CONGRATULATIONS UPON YOUR RECOGNITION AS A COMPRE-
HENSIVE CANCER CENTER. ALL OF US WHO HAVE SEEN YOUR
EFFORTS FEEL YOU AND YOUR STAFF HAVE DONE A SUPERB JOB
(CONTINUED ON PAGE 2)**

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